Innovative Immuno-oncology Antibody Drug Market Study

Confidential For

Leads Biolabs
维 立 志 博

Date: July 17

For and on behalf of
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Title: Consulting Director

Frost & Sullivan
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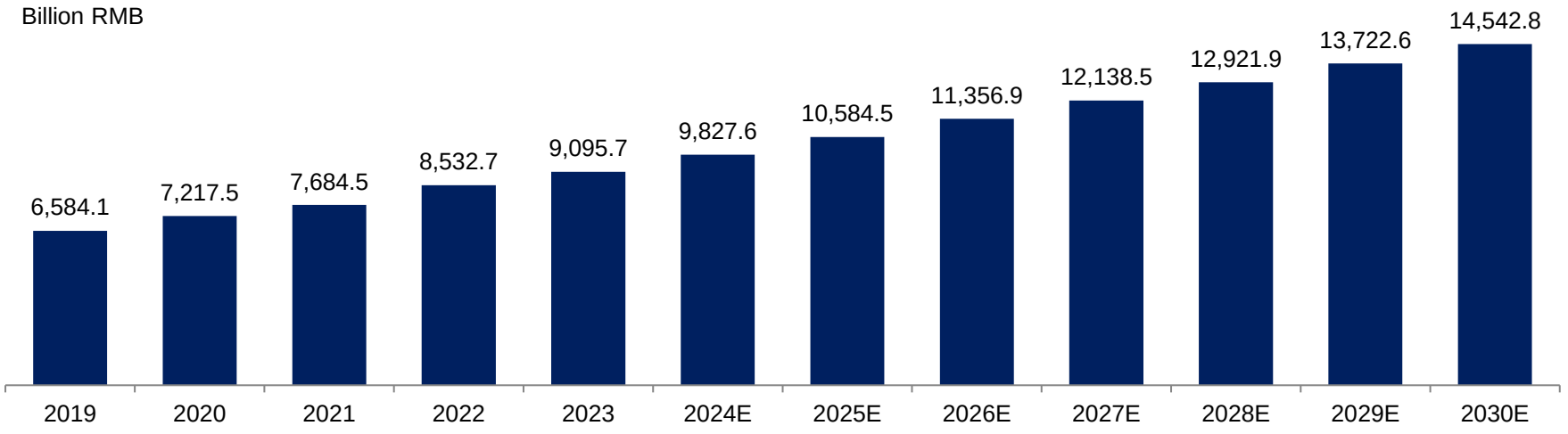
Total Healthcare Expenditure in China, 2019-2030E

- In China, the total healthcare expenditure reached RMB 9,095.7 billion in 2023 at a CAGR of 8.4% from 2019. It is projected to further increase to RMB 11,356.9 billion in 2026, representing a CAGR of 7.7% from 2023. It is estimated that the number would achieve RMB 14,542.8 billion in 2030, representing a CAGR of 6.4% from 2026 to 2030.

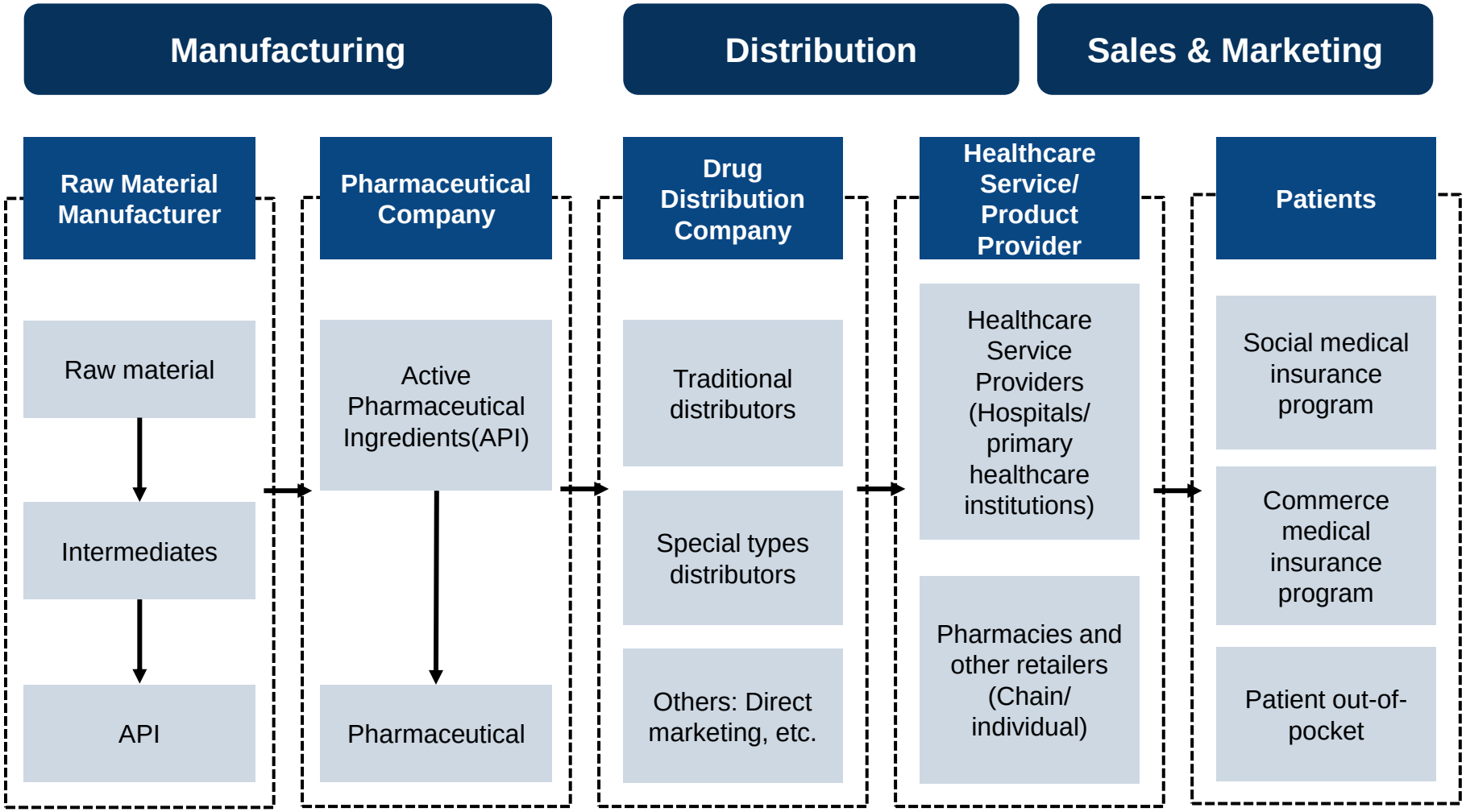
Total Healthcare Expenditure in China, 2019-2030E

Period	CAGR
2019-2023	8.4%
2023-2026E	7.7%
2026E-2030E	6.4%



Source: National Health Commission, Frost & Sullivan Analysis

Industry Chain of Pharmaceutical Industry



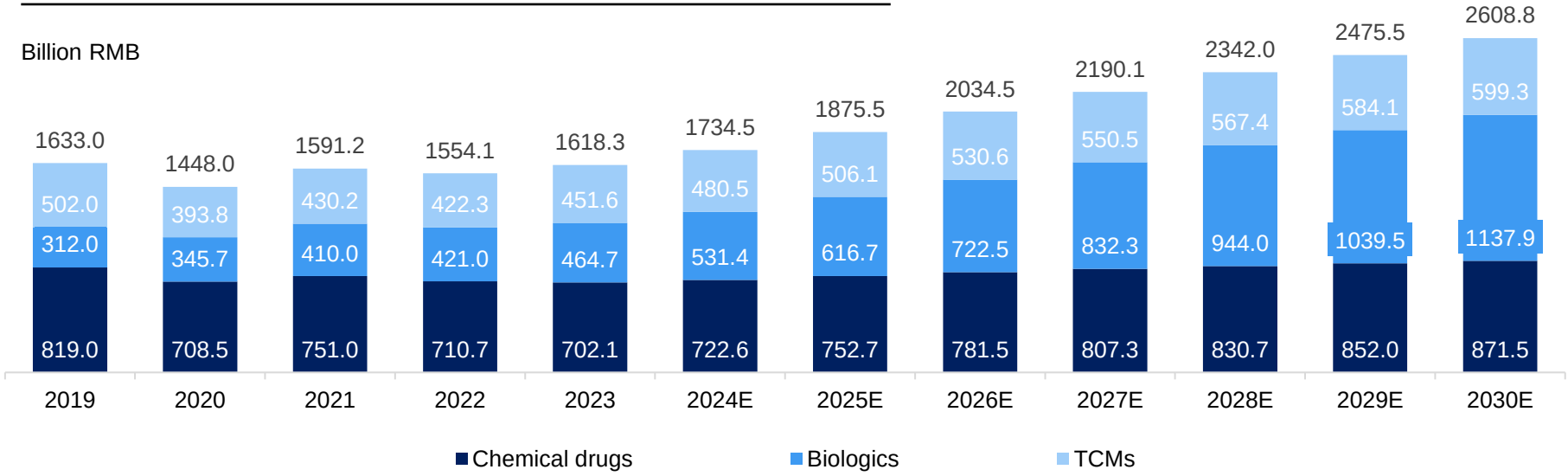
Source: Frost & Sullivan Analysis

Breakdown of China Pharmaceutical Market by Chemical Drugs, Biologics and TCMs, 2019-2030E

- China pharmaceutical market is composed by three segments, namely chemical drugs, biologics and Chinese medicines (TCMs), among which chemical drugs account for the largest market share. The size of China pharmaceutical market was RMB 1618.3 billion in 2023, and is expected to reach RMB 2034.5 billion and RMB 2608.8 billion in 2026 and 2030 respectively, representing a CAGR of 7.9% from 2023 to 2026 and 6.4% from 2026 to 2030.

Breakdown of China Pharmaceutical Market by Chemical Drugs, Biologics and TCMs, 2019-2030E

CAGR	Chemical Drugs	Biologics	TCMs	Total
2019-2023	-3.8%	10.5%	-2.6%	-0.2%
2023-2026E	3.6%	15.8%	5.5%	7.9%
2026E-2030E	2.8%	12.0%	3.1%	6.4%



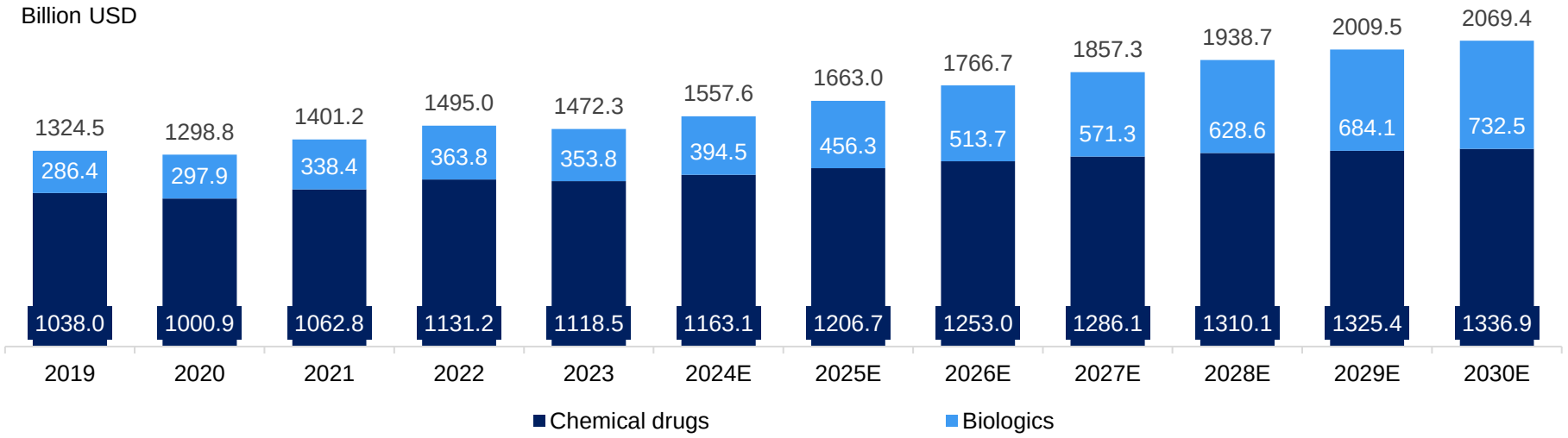
Source: Frost & Sullivan Analysis

Breakdown of Global Pharmaceutical Market by Chemical Drugs and Biologics, 2019-2030E

- Global pharmaceutical market is composed by two segments, namely chemical drugs, biologics, among which chemical drugs account for the largest market share. The size of Global pharmaceutical market was USD 1472.3 billion in 2023, and is expected to reach USD 1766.7 billion and USD 2069.4 billion in 2026 and 2030 respectively, representing a CAGR of 6.3% from 2023 to 2026 and 4.0% from 2026 to 2030.

Breakdown of Global Pharmaceutical Market by Chemical Drugs and Biologics, 2019-2030E

CAGR	Chemical Drugs	Biologics	Total
2019-2023	1.9%	5.4%	2.7%
2023-2026E	3.9%	13.2%	6.3%
2026E-2030E	1.6%	9.3%	4.0%



Source: Frost & Sullivan Analysis

Market Trends and Key Growth Drivers of Global Biologics Market

Efficacy of Biologics	• Because biologics such as fusion proteins and monoclonal antibodies can specifically bind to designated antigens, they have been shown to have promising efficacy when used to treat cancer and autoimmune diseases, with high specificity, faster onset and fewer side effects. Such superior efficacy of biologics results in growing acceptance among patients and doctors, which stimulates demand and drives market growth.
Development in Biotechnology and Increasing Investment in R&D	• The application of biotechnology in pharmaceutical science has brought a series of breakthroughs in the development of new biologics. For instance, as antibody-drug technology continues to evolve, antibody drugs have generated many innovative strategies, such as dual antibodies and antibody-drug conjugates (ADCs). The developments in biotechnology may also be able to increase the production yield of biologics, leading to substantially lower production costs. Global research and development investment for biologics is expected to increase in the future and is expected to bring more products into the market. The development in biotechnology and the continuous launch of new products will further drive the growth of the global biologics industry.
Increasingly More Biologics Approvals	• From 2018 to 2020, the number of biologics approved by FDA is slightly lower the number of chemical drugs, while it exceeded between 2021 and 2023, with more than 100 biologics getting approved, indicating a boost in the biologics industry.

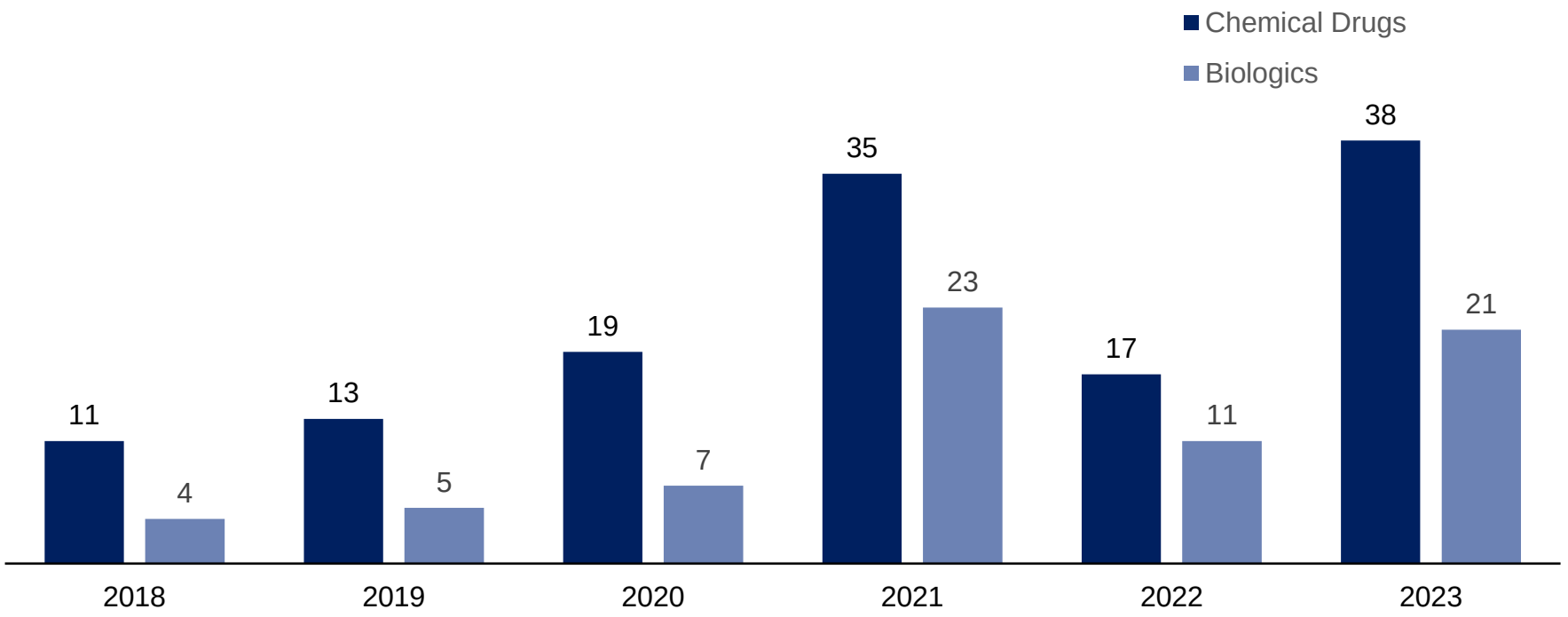
Source: Frost & Sullivan Analysis

Market Trends and Key Growth Drivers of China Biologics Market

Growing Disease Incidence	• Driven by unhealthy lifestyles, pollution, and the aging population, the number of patients with chronic diseases in China continues to expand. For example, in the therapeutic areas of Company's products, total annual cancer incidence in China increased from 4,521.4 thousand in 2019 to 4,929.0 thousand in 2023, and this number is expected to reach 5,645.3 thousand in 2030. In the area of metabolic diseases, prevalence is also expected to increase. Biological drugs have excellent clinical effects on many chronic diseases, including cancer and diabetes, and the huge patient population pool will further drive market growth.
Increasing R&D Investments	• The biologics industry is capital-intensive and requires heavy investment in research and development. In China, the research and development spending on biologics increased from RMB76.2 billion to RMB142.0 billion, with a CAGR of 16.8% from 2017 to 2021. R&D expenditure on biologics is expected to reach RMB308.8 billion in 2030, indicating a promising future with more biologics approved and brought to the market.
Regulatory Reform and Favorable Government Policies	• The China government has established a set of regulations and policies to support the development of China's biologics market. In particular, Jiangsu and Nanjing governments have introduced several policies to promote open innovation and the high-quality development of the biologics market. These includeLife and Health Science and Technology Innovation Action Plan (《生命健康科技創新行動計劃》), the Policy Measures on Promoting the High-Quality Developmentof the Jiangsu Province's Biomedical Industry (《關於促進全省生物醫藥產業高質量發展的若幹政策措施》), and Several Policy Measures on Promoting High-Quality Development of the Nanjing City's Biomedical Industry (《關於促進全市生物醫藥產業高質量發展的若幹政策措施》). Specifically, in the Plan and the Measures, to support the research and development of innovative drugs, the Jiangsu and Nanjing governments would provide financial incentives to companies for innovative drugs that have completed different development stages.
Increasing Affordability and Healthcare Awareness	• In China, the per capita disposable income has grown rapidly from RMB30,733 in 2018 to RMB39,218 in 2023. This increase in disposable income is reflected in the increase in healthcare expenditure, and this trend is expected to continue. In recent years, the inclusion of biologics into NRDL further increases accessibility and affordability of biologics. For example, some of Company's products such as bevacizumab and denosumab have already been included in the NRDL. Increasing affordability brought by NRDL inclusion along with increased health awareness would further drive market growth as sales volume is expected to increase. In addition, in November 2021, China's 6th centralized drug procurement just involved insulin, which is the first biological drug involved in the centralized procurement program. After the centralized purchase, the average price cut and highest price cut of insulin were 48% and 74%, respectively, which sets an example for improvement in biologics affordability through centralized drug procurement. With the increasing biologics affordability and the improvement of health awareness, domestic demand for biological drugs will burgeon in the future

Innovative Drugs Approved by NMPA, 2018-2023

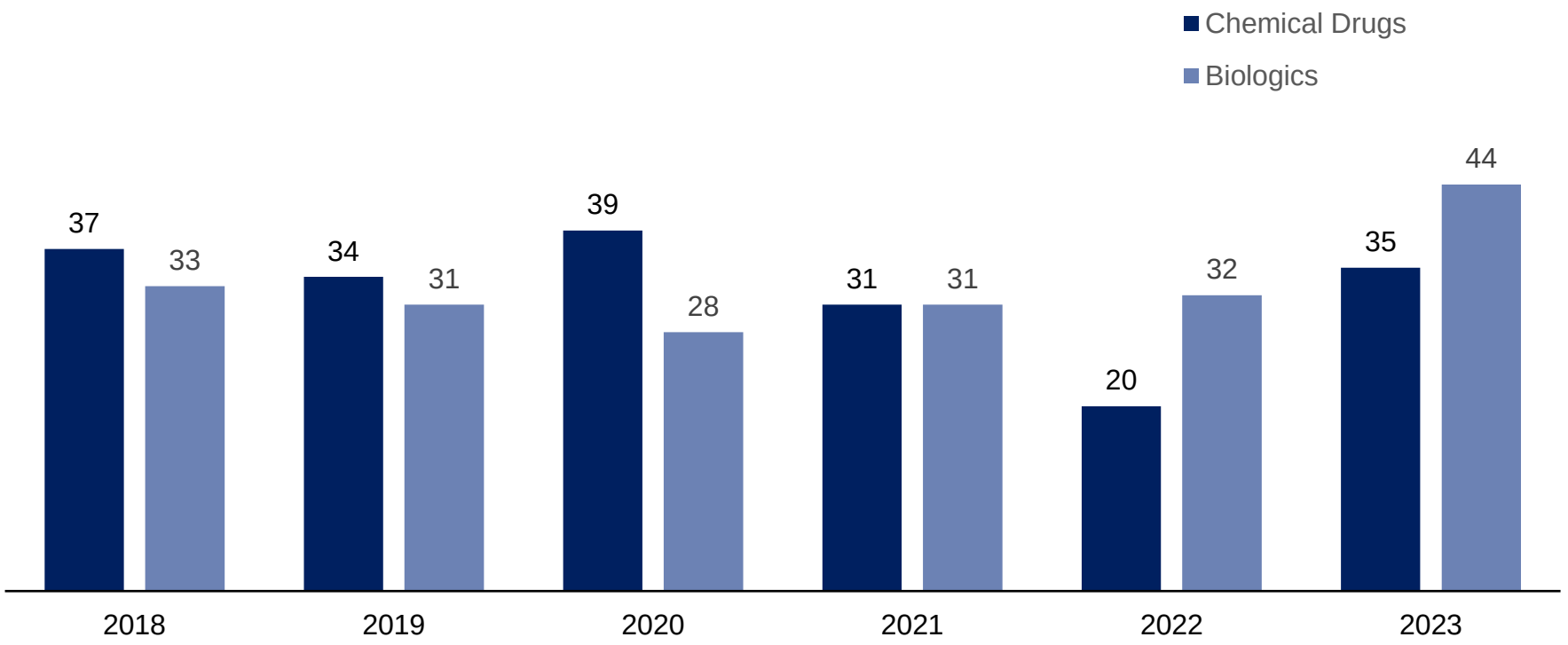
- The following bar chart set forth the number of small molecule drugs approved by NMPA from 2018 to 2023. The number of chemical drugs is relatively more than approved biologics.



Source: NMPA, Frost & Sullivan Analysis

Innovative Drugs Approved by FDA, 2018-2023

- The following bar presents the number of small molecule drugs approved by FDA from 2018 to 2023.



Source: FDA, Frost & Sullivan Analysis

Favorable Government Policy of Pharmaceutical Industry

Review of Clinical Trial and New Drug Application

Release Date	Issuing Authority	Policies	Comments
Aug, 2015	State Council	*Opinions of the State Council on Reform of the System of Evaluation, Review and Approval of Drugs and Medical Devices* 《国务院关于改革药品医疗器械审评审批制度的意见》	• Accelerating the review and approval of innovative drug trials. • Implementing specific review, evaluation and approval system to accelerating the review and approval process for innovative drugs that are in use of prevention and treatment of AIDS, malignant tumors, major infectious diseases, rare diseases, as well as drugs listed in national science and technology projects and national key R&D programs.
Mar, 2016	State Council	*Guiding Opinions of the General Office of the State Council on Promoting the Sound Development of the Medical Industry* 《国务院办公厅关于促进医药产业健康发展的指导意见》	• Deepening review and approval system reforms. Establishing a more scientific and efficient review and approval system for drug and medical devices. • Strengthening the construction of review teams, and recruiting experts and scholars with international review and approval experience.
Oct, 2016	State Council	*Healthy China 2030* 《“健康中国2030”规划纲要》	• Strengthening drug safety supervision. • Deepening the reform of the review and approval system for pharmaceuticals (medical devices), establishing review and approval system based on clinical curative effects. • Improving the approval standards for drug (medical devices).
Dec, 2017	General Office of the CPC Central Committee and the General Office of the State Council	*Opinions of Encouraging Drug Innovation to Implement Priority Review and Approval* 《总局关于鼓励药品创新实行优先审评审批的意见》	Drug registration with obvious clinical value meets one of the following requirements: • Application for registration of innovative drugs not listed and sold in China or abroad. • Application for registration of innovative drugs transferred to China. • Drug registration applications with advanced preparation technology, innovative treatment methods and obvious therapeutic advantages.

Source: Government Website, Frost & Sullivan Analysis

Favorable Government Policy of Pharmaceutical Industry

Review of Clinical Trial and New Drug Application

Release Date	Issuing Authority	Policies	Comments
May, 2018	CFDA	*Notice for Optimizing the Examination, Assessment and Approval of Drug Registration* 《关于优化药品注册审评审批有关事宜的公告》	In order to improve the efficiency of review and approval of innovative drugs as well as simplify the procedure: • The review and approval for rare diseases that seriously endanger life with no effective treatment could be sped up through communication system between CDE and applicants. • The clinical data obtained overseas with no ethnic difference could directly apply for drug launch registration.
Jul, 2018	CFDA	*Technical Guidelines for Accepting Data from Overseas Clinical Trials of Drugs* 《接受药品境外临床试验数据的技术指导原则》	• In order to encourage the synchronous drug R&D both domestic and abroad, the acceptable overseas clinical trials data are clarified. • The overseas R&D of generic drug with complete and assessable bioequivalence data can also be used for registration applications.
Jul, 2018	CFDA	*Announcement on Adjusting the Examination and Approval Procedure of Drug Clinical Trials* 《关于调整药物临床试验审评审批程序的公告》	• Drug clinical trial filing system: The drug clinical trial can be carried out according to the submitted scheme if the applicant fails to receive the negative or doubtful opinions from CDE within 60 days from the accepted and payment date of the application.
Oct, 2018	CFDA	*Announcement on the urgent clinical need for approval of new drugs abroad* 《关于临床急需境外新药审评审批相关事宜的公告（2018年第79号）》	Establish a special channel for review and approval of overseas innovative drugs that are urgently needed, which has launched in the United States, the EU or Japan in the past 10 years but not in China, meeting one of the following circumstances: • Drugs for the treatment of rare diseases • Drugs for serious life-threatening diseases without effective treatment • Drugs have obvious clinical advantages for serious life-threatening diseases. The innovative drugs from abroad can be declared for manufacturing directly without domestic clinical data after demonstration of no ethnic difference.

Source: Government Website, Frost & Sullivan Analysis

Favorable Government Policy of Pharmaceutical Industry

Review of Clinical Trial and New Drug Application

Release Date	Issuing Authority	Policies	Comments
Sep, 2019	NHC, NHSA, NMPA	*Notice for the Publication of the Health China_ Implementation Plan for Cancer Prevention (2019-2022 edition)* 《关于印发健康中国行动——癌症防治实施方案（2019—2022年）的通知》	• Establish a comprehensive clinical evaluation system for anticancer drugs. • Speed up the approval of new anticancer drugs at home and abroad.
Nov, 2019	NMPA	*Notice on Soliciting Opinions on the Working Procedures of Breakthrough Therapeutics and the Priority Review and Approval Process* 《关于突破性治疗药物工作程序和优先审评审批工作程序征求意见的通知》	• For innovative drugs or improved new drugs that are used to prevent or treat severely life-threatening diseases, and that have no effective prevention measures or have sufficient evidence to show obvious clinical advantages compared with existing therapies, they can apply for Breakthrough Treatment Drugs. • Breakthrough Treatment Drugs can be reviewed and approved first.
Apr, 2020	NMPA, NHC	*Announcement on the Release of Quality Management Practices for Drug Clinical Trials* 《关于发布药物临床试验质量管理规范的公告》	• Deepen the reform of drug evaluation and approval system and encourage innovation. • Further promote standardized research and improve the quality of drug clinical trials in China.
Dec, 2020	NMPA	*Guidelines for Statistical Design of Antitumor Drug Clinical Trials (Trial)* 《抗肿瘤药物临床试验统计学设计指导原则（试行）》	• The statistical methods for the commonly used efficacy endpoints are proposed in the guidelines, and the statistical design requirements are putted forward from the perspectives of exploratory and confirmatory trials.
Feb, 2022	CDE	*Notice for soliciting opinions on the "CDE to Accelerate the Review Procedures for Innovative Drug Applications (Trial)* 关于《药审中心加快创新药上市申请审评工作程序（试行）》征求意见的通知	• Encouraging the research and development of new drugs to meet clinical drug needs. • Speeding up the review of innovative drugs.

Source: Government Website, Frost & Sullivan Analysis

Favorable Government Policy of Pharmaceutical Industry

Review of Clinical Trial and New Drug Application

Release Date	Issuing Authority	Policies	Comments
March, 2023	CDE	Guidelines for the applicability of single-arm clinical trials to support new drug applications for anti-tumor drugs 《单臂临床试验用于支持抗肿瘤药上市申请的适用性技术指导原则》	• Clarify the current scientific understanding of the applicability of single-arm clinical trials to support new drug applications for anti-tumor drugs, and guide companies to better assess whether it is appropriate to conduct single-arm clinical trials as key clinical studies after completing early studies.
April, 2022	CDE	*CDE to Accelerate the Review Procedures for Innovative Drug Applications* 《药审中心加快创新药上市申请审评工作程序（试行）》	• Encouraging the research and development of new drugs to meet clinical drug needs. • Speeding up the review of innovative drugs.
Nov, 2023	NMPA	*the Measures for the Supervision and Inspection of Drug Clinical Trial Institutions (Trial)* 《药物临床试验机构监督检查办法（试行）》	• According to the nature and purpose of the inspection, inspections carried out on testing institutions are divided into daily supervision inspections, reasoned inspections and other inspections. Different types of inspections can be combined.
Dec,2023	CDE	*Guiding Principles for Clinical Safety Evaluation of New Drugs* 《新药临床安全性评价技术指导原则》	• Clinical safety evaluation of new drugs is an important basis for benefit-risk assessment of new drugs. This document aims to provide scientific methods and technical guidance for the clinical safety evaluation of new drugs.

Source: Government Website, Frost & Sullivan Analysis

Favorable Government Policy of Pharmaceutical Industry

Review of Innovation Encouragement

Release Date	Issuing Authority	Policies	Comments
Mar, 2016	State Council	*Guiding Opinions of Promoting the Healthy Development of the Pharmaceutical Industry* 《国务院办公厅关于促进医药产业健康发展的指导意见》	• Accelerating the development of innovative drugs and biological products with major clinical needs; • Speeding up the promotion of green and intelligent pharmaceutical production technologies; • Strengthening scientific and efficient supervision; • Promoting the development of industrial internationalization.
Mar, 2016	CFDA	*Plan of the System of the Holders of Drug Marketing Licenses* 《药品上市许可持有人制度试点方案》	• Drug research and development institutions or scientific research personnel in the pilot administrative areas may serve as drug applicants for registration, and submit applications for drugs clinical trials and marketing.
Oct, 2016	State Council	*Healthy China 2030* 《“健康中国2030”规划纲要》	• Strengthening technical innovation by forming a Government-Industry-University-Research Cooperation efficient system; • Improving the quality control system of drug and medical devices. By 2030, quality standards for drugs and medical devices would be fully integrated with international standards.
Dec, 2016	State Council	*13th Five-Year Plan for National Strategic Emerging industry Development* 《“十三五”国家战略性新兴产业发展规划》	• Accelerating the innovation and industrialization of new drugs. • Promoting the development of high-tech biosimilar drugs such as monoclonal antibodies, long-acting recombinant proteins, and third-generation insulin, and increasing the accessibility of drugs to patients.
May, 2017	CFDA	*Policies of Encouraging Drug Medical Equipment Innovation to Implement Drug Medical Equipment Life Cycle Management* 《关于鼓励药品医疗器械创新实施药品医疗器械全生命周期管理的相关政策（征求意见稿）》	• Accelerating the informationization of review and approval system. • Formulating the technical requirements for the electronic submission of drug and medical device registration. • Improving the general electronic documentation system.

Source: Government Website, Frost & Sullivan Analysis

Favorable Government Policy of Pharmaceutical Industry

Review of Innovation Encouragement

Release Date	Issuing Authority	Policies	Comments
Oct, 2017	CFDA	*Reform of Review and Approval System for Drugs and Medical Devices to Encourage Innovation (the Opinion)* 《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》	• Seek to streamline the clinical trial process and shorten the time line. • Provid for special fast-track approval for two kinds of drugs and medical devices: (i) new drugs and devices in urgent clinical need; (ii) drugs and devices for rare diseases. • Encouraging innovation and protect innovators through (i) the adoption of a patent linkage system, (ii) restoration of patent term, (iii) protection of innovator's data.
Dec, 2017	CFDA	*Opinions of Implementing Priority Review and Approval to Encourage Drug Innovation* 《总局关于鼓励药品创新实行优先审评审批的意见》	• Establish a comprehensive evaluation system with technical review as the core, in combination with risk-based on-site inspection and sample testing. • Accept foreign data to support MAA if meet China requirements; • Accept application of new dosage form based on clinical needs; • Implement conditional approvals
Jan, 2018	CFDA	*Reform of Review and Approval System for Drugs and Medical Devices to Encourage Innovation (the Opinion)* 《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》	• Promote the integration of drug registration technical standards with international standards. • Accelerate the drug examination and approval process. • Strengthening the management for drug life cycle.
Jan, 2018	CFDA	*Opinions of Strengthening and Promoting Scientific and Technological Innovation in Food and Drugs* 《关于加强和促进食品药品科技创新工作的指导意见》	• Encourage innovation and protect innovators through (i) Improve the support of scientific and technological innovation in the field of food and drug. (ii) Establish and improve the supporting network for scientific research. (iii) Enhance companies' technological innovation capability. (iv) Strengthen the construction of major technological innovation platforms. (v) Establish incentive and reward mechanism for talents.

Source: Government Website, Frost & Sullivan Analysis

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Mar, 2018	CFDA	*Guidance for Pharmaceutical Research in Phase III Clinical Trials of Innovative Drugs (Chemicals)* 《创新药(化学药) III期临床试验药学研究信息指南》	• Encourage R&D of new and innovative drugs. • Accelerate establishment of the standard system of technical guidelines for R&D and examination and approval process of innovative pharmaceuticals. • Improve the quality and efficiency new R&D review.
Feb, 2019	MoF	*Notice on VAT policy for rare disease drugs* 《关于罕见病药品增值税政策的通知》	• To encourage the development of the rare disease pharmaceutical industry and reduce the cost of medication for patients. VAT general taxpayers who produce, wholesale and retail rare disease drugs can pay VAT at a 3% levy rate according to the simple method, starting from March 1, 2019.
Jul, 2019	NMPA	*Announcement on Further Improving the Correlated Matters of Drug Related Evaluation, Approval and Supervision* 《关于进一步完善药品关联审评审批和监管工作有关事宜的公告》	• Encourage innovative drugs by optimizing the approval process. • Further clarifies the review, approval and supervision of the association between active pharmaceutical ingredients, excipients, and immediate packaging materials and containers as well as pharmaceutical products.
Aug, 2019	NMPA	*Pharmaceutical Administration Law of the People's Republic of China* 《中华人民共和国药品管理法》	• It is the second major systematic and structural amendment to the Pharmaceutical Administration Law since its first promulgation in 1984. • Focus on supporting clinical value-oriented drug innovations which have significant effects on human disease. Encourage the development of new medicines with new treatment mechanism on severely life-threatening diseases, rare diseases and children's diseases. • Establish related laws of clinical trial acquiescence system, clinical trial institution filing management system, priority review and approval system, conditional approval system, etc. • Established a listing authorization system to encourage innovation.

Source: Government Website, Frost & Sullivan Analysis

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Release Date	Issuing Authority	Policies	Comments
Jul, 2020	NMPA	*Announcement on the Release of Three Documents such as the Work Procedure for the Evaluation of Breakthrough Therapy Drugs (trial)* 《关于发布《突破性治疗药物审评工作程序（试行）》等三个文件的公告》	• To cooperate with the implementation of Drug Registration Administration Measures, hese work procedures are developed: (i) Review and Evaluation Procedures for Breakthrough Therapy Drugs (Trial) (ii) Review and Approval Procedures for conditionally approved marketing application of drugs (Trial) (iii) Procedure for Priority Evaluation and Approval of Drug Marketing Authorization (Trial)
Sep, 2020	MoF	*Announcement on the Release of the Second Batch on Anticancer Drugs and Orphan Drugs Applicable to the VAT Policy* 《关于发布第二批适用增值税政策的抗癌药品和罕见病药品清单的公告》	• In order to encourage the development of pharmaceutical industry, and reduce the cost of drugs for patients, the second list includes 39 pharmaceutical products, 6 active pharmaceutical ingredients of anticancer drugs and 14 pharmaceutical products of orphan drugs. VAT general taxpayers who produce, wholesale and retail those drugs can pay VAT at a 3% levy rate according to the simple method, starting from Octor 1, 2020.
Dec. 2020	NHSA	*Announcement on the "Internet + healthcare" "five one" service action* 《关于深入推进“互联网+医疗健康” “五个一”服务行动的通知》	• Support the pharmaceutical industry by making the payment process quicker and easier, simplifying the healthcare services and applying digitalization methods.
Sep. 2021	NHSA, NMPA	*The “14th Five-Year Plan” National Drug Safety and High-quality Development Plan Promotion* 《“十四五”国家药品安全及促进高质量发展规划印发》	• Support high-quality industrial development of the regulatory environment and system reform. • Approving many innovative drugs in urgent clinical need. • Accelerate the listing of innovative drugs with clinical value and innovative medical devices as soon as possible in the domestic market. • Formulate and revise 2650 standards and 480 new guidelines on drugs, medical devices, and cosmetics.

Source: Government Website, Frost & Sullivan Analysis

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Dec. 2021	NHSA	*Guidance from the National Health Insurance Administration and the State Administration of Traditional Chinese Medicine on Medical Insurance Support for the Development of Traditional Chinese Medicine Inheritance and Innovation* 《国家医疗保障局和国家中医药管理局关于医保支持中医药传承创新发展的指导意见》	• Medical insurance to support the development of Chinese medicine heritage and innovation • Policy to include eligible TCM institutions into the medical insurance designated points and to include "Internet+" TCM services into the scope of medical insurance payment
May, 2022	The State Council	*14th Five-Year National Health Plan* 《十四五国民健康规划》	• Encourage the research and development of new drugs for the treatment of major diseases that are urgently needed in clinical settings, and support the research and development of high-quality generic drugs. • Deepen the reform of the review and approval system for drugs and medical devices, and speed up the review and approval of innovative drugs, urgently clinically needed drugs and medical devices, and rare disease treatment drugs.
July, 2023	National Healthcare Security Administration	*Rules for Negotiating Drug Contract Renewals* 《谈判药品续约规则》	• For Category 1 chemical drugs, Category 1 therapeutic biological agents, Category 1 and Category 3 proprietary Chinese medicines approved in accordance with the current registration management methods, when the renewal triggers the price reduction mechanism, manufacturers can apply for renewal through renegotiation. The government will organize experts to calculate through the program, and the reduction in negotiated renewal does not need to be higher than the reduction stipulated in the simple renewal.

Source: Government Website, Frost & Sullivan Analysis

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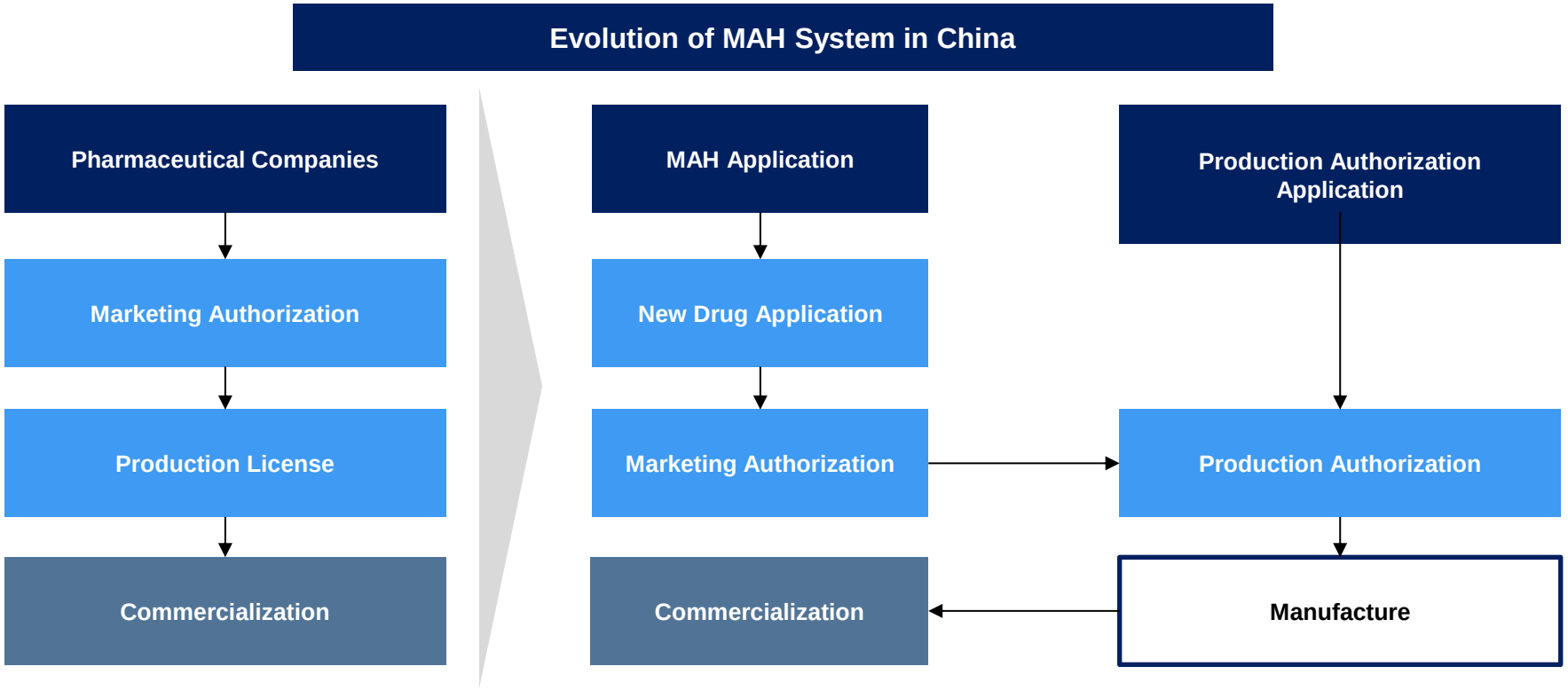
Review of Innovation Encouragement

Release Date	Issuing Authority	Policies	Comments
Jan, 2024	General Office of the CPC Central Committee, The State Council	Pudong New Area Comprehensive Reform Pilot Implementation Plan (2023-2027)	• Establish a collaborative relationship among medical institutions, universities, and research institutes to strengthen clinical research cooperation, allow new launched products to be priced according to similar international drugs in accordance with relevant regulations, and support the development of innovative drugs and medical device.
Feb, 2024	National Medical Insurance Administration	*Notice on establishing a first-time price formation mechanism for newly launched chemical drugs to encourage high-quality innovation (Draft for Comments)* 关于建立新上市化学药品首发价格形成机制 鼓励高质量创新的通知（征求意见稿）	• For newly launched chemical drugs, manufacturers can self-evaluate from the perspective of pharmacy, clinical value and evidence-based evidence based on the evaluation scale published by the medical insurance department. The self-evaluation score can reflect its innovativeness. The stronger the innovation, the higher initial price that the drug can set.

Source: Government Website, Frost & Sullivan Analysis

Policy Analysis of Marketing Authorization Holder (MAH)

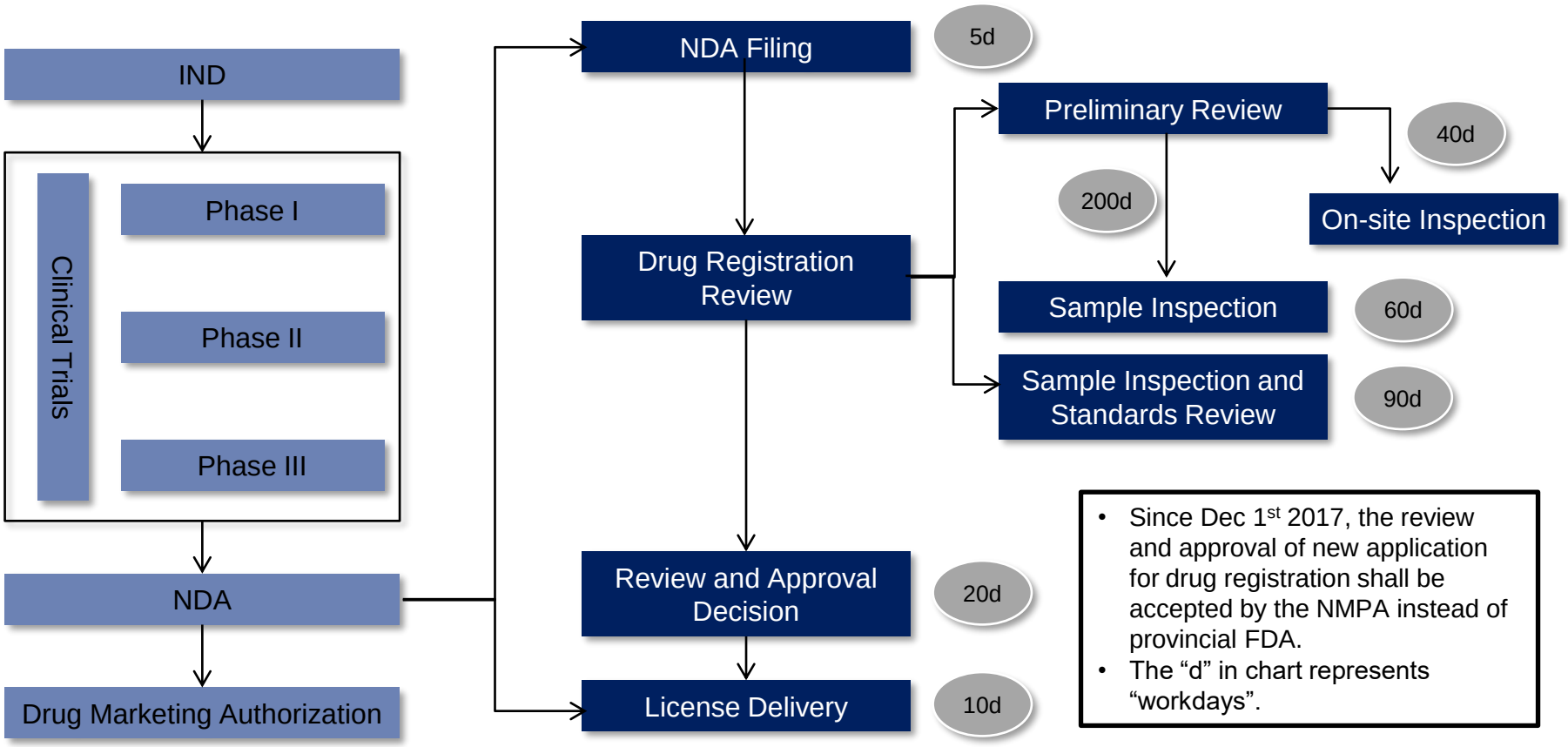
- MAH system enables the R&D organizations or personnel to apply for and obtain drug marketing authorizations and drug approval license, and the MAHs can entrust the CMOs to manufacture drugs instead of obtaining production license themselves, so that they can focus on R&D rather than allocate the manpower and investment on manufacturing.
- MAH system helps to promote R&D innovation, accelerate industrial restructuring and optimize resource allocation.



Source: Government Website, Frost & Sullivan Analysis

Drug Registration Procedure in China

- According to Provision for Drug Registration《药物注册管理办法》 and Notice of Adjustment of Drug Registration Acceptance 《关于调整药品注册受理工作的公告》 in 2017, the drug registration has changed in processing time limitation and authorities supervising NMPA reviews to accelerate the NDA review and approval.



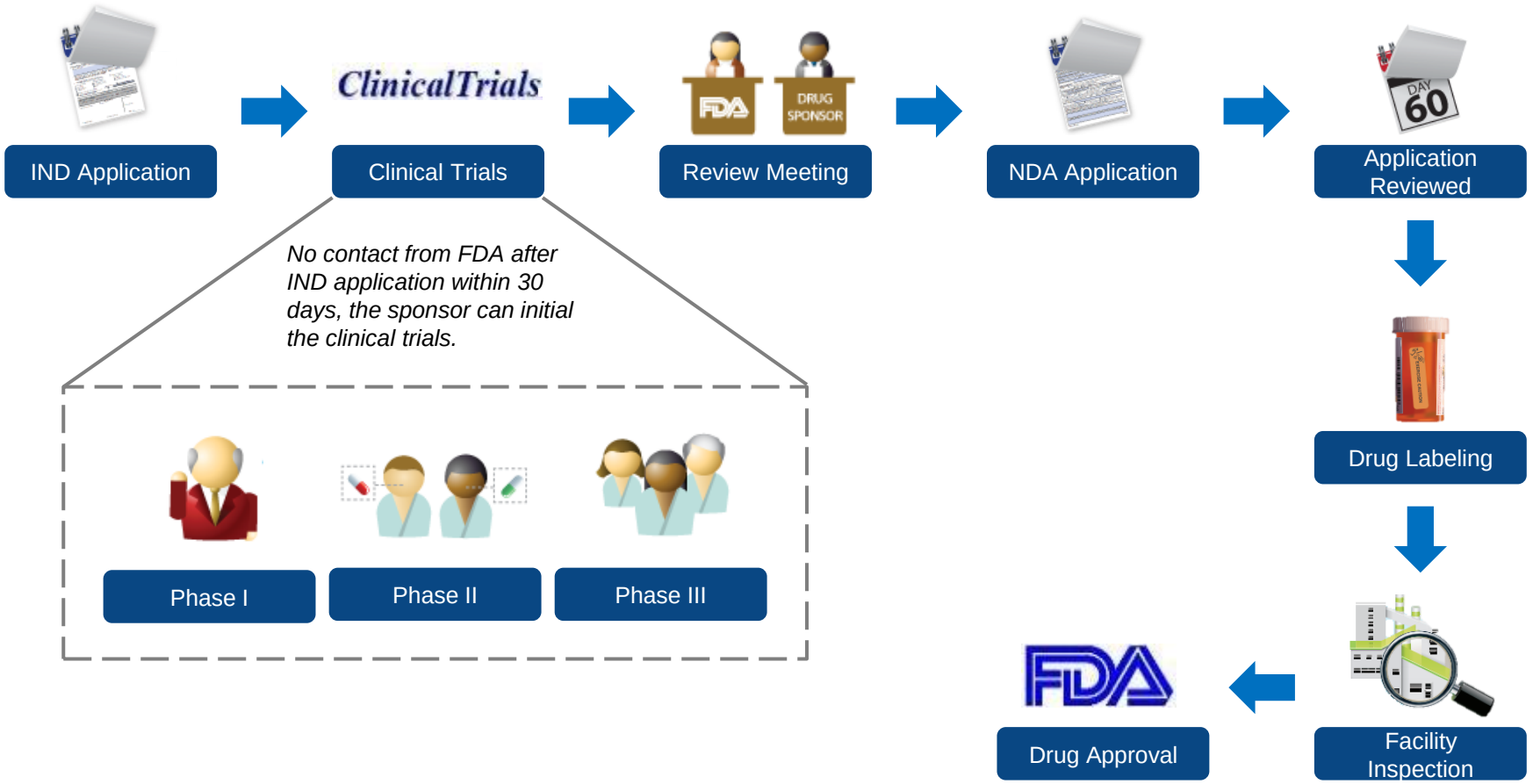
- Since Dec 1st 2017, the review and approval of new application for drug registration shall be accepted by the NMPA instead of provincial FDA.
- The “d” in chart represents “workdays”.

Note: The Procedure is a general approval pathway. In reality, approval pathway may vary case by case.

Source: CMA, Frost & Sullivan analysis

Drug Registration Procedure in the US

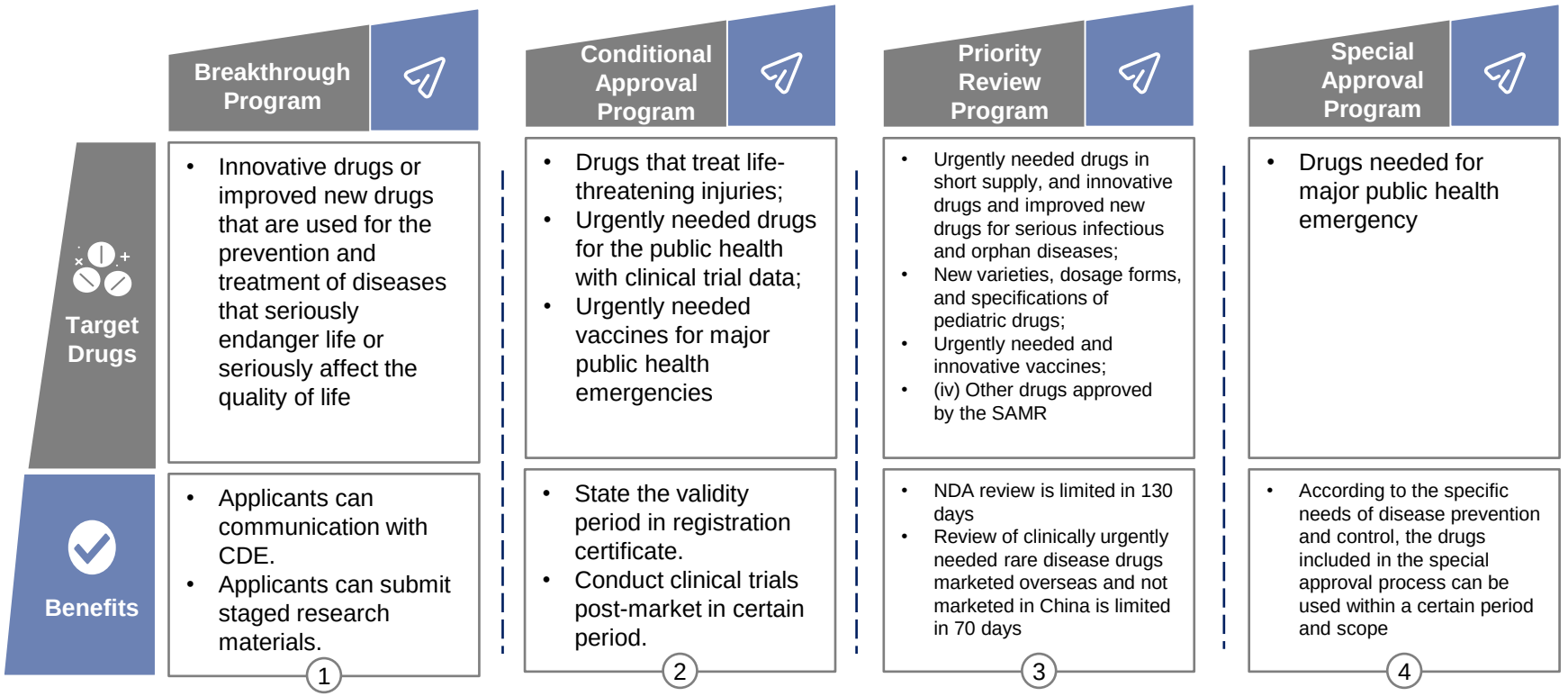
- Drug registration in the US needs to comply with Federal Food, Drug and Cosmetic Act (FD&C Act), which stipulates the application filling and clinical trial requirements from IND application to drug approval.



Source: FDA, Frost & Sullivan analysis

Grants Programs to Innovative Drugs in China

- On March 30, 2020, the State Administration for Market Regulation (SAMR), released a revised Drug Registration Regulation (Revised DRR) as part of its efforts to strengthen and streamline its regulation of the pharmaceutical industry, which went into effect on July 1, 2020. There are four programs included in the regulation, target drugs and benefit of each program are illustrated as follows:



Source: Frost & Sullivan Analysis

FDA Expedited Programs for New Drug Approval

- FDA has developed four distinct and successful approaches to make innovative drugs or those with advantages over existing treatments as soon as possible. FDA expedited programs aims to help spur the development of new therapies for serious conditions.

1 Fast Track

Application Timing

- This request can be initiated at any time during the drug development process, even if clinical trial data are not yet available

Response Time

- Within 60 days from the date of receipt of application.

Features

- Hold more frequent meetings with the FDA to discuss drug development plans and clinical trial protocols
- Rolling review

Qualifying Criteria

- For serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need

2 Breakthrough Therapy

Application Timing

- It is recommended that a request for breakthrough therapy designation be submitted no later than the end-of-phase II meeting

Response Time

- Within 60 days from the date of receipt of application

Features

- Intensive guidance on efficient drug development
- Organizational commitment
- Rolling review

Qualifying Criteria

- For serious condition and preliminary clinical evidence indicates that the drug may be a substantial improvement over available therapies

3 Accelerated Approval

Application Timing

- During the study period, the applicant should always discuss with the review authority the possibility of accelerated licensure

Response Time

- No specific instructions

Features

- Approval based on an effect on a surrogate endpoint of an intermediate clinical endpoint that is reasonable likely to predict a drugs clinical benefit

Qualifying Criteria

- For serious condition and demonstrates an effect on a surrogate endpoint that is reasonable likely to predict clinical benefit or on a clinical endpoint that can be measured earlier

4 Priority Review

Application Timing

- Submit concurrently with the original NDA, BLA, or efficacy supplement application

Response Time

- Within 60 days from the date of receipt of application

Features

- Shorter clock for review of marketing application(6 months compared with the 10-month standard review)

Qualifying Criteria

- For serious condition and, if approved, would provide a significant improvement in safety or effectiveness

Source: FDA, Frost & Sullivan analysis

Overview of Healthcare Insurance System in China

Public Medical Insurance	**UEBMIS**	**Urban Employee Basic Medical Insurance Scheme (UEBMIS)** • The scheme for urban employees, which is jointly funded by employers and employees, was established in 1998 to provide reimbursement for medical services and drugs. • Under UEBMIS, employees including retirees are entitled to the healthcare insurance benefits. Generally, it is funded by (i) monthly payments from the beneficiary, such as the employee, and (ii) co-payments made by the employer of the beneficiary, both of which are subject to a ratio set forth by the local Labor and Social Security Authority. The ratio is calculated based on the monthly salary of the employee.
	URBMIS & NRCMIS	**Urban Resident Basic Medical Insurance Scheme (URBMIS)** • The scheme for urban residents, financed by governments and individuals, was set up in 2007, and is now administered by the MOHRSS to provide coverage for major illnesses for urban residents not covered under UEBMIS. • Most of its participants are urban residents who are currently unemployed or retired. Participants of the URBMIS are required to contribute to the payment of insurance premiums on a monthly basis. **New Rural Cooperative Medical Insurance Scheme (NRCMIS)** • The NRCMIS piloted in 2003 given the government's dedication to establish the rural cooperative medical care system so as to improve access to medical services and drug supply in rural areas. The NRCMIS is funded by allocations from the central government, subsidies from local governments and fees paid by rural Chinese who participate the system voluntarily. **Consolidation of URBMIS and NRCMIS** • In 2016, a few provinces in China have piloted consolidation of NRCMIS and URBMIS because of their similarities in funding Source and levels, which paves the way towards a nationwide, consolidated, medical insurance system. Opinions of Consolidation of URBMIS and NRCMIS (《国务院关于整合城乡居民基本医疗保险制度的意见》) required all provinces must put forward implementation plans of such consolidation by the end of 2016.
	Medical Aid Scheme	Medical aid schemes are subsidized by local and central government funds and private donations and vary according to the local financial situation, to benefit low income patients with non-reimbursement expenses for inpatient and outpatient services.
Commercial Medical Insurance		Private medical institutions are pressing for patient reimbursement through the social insurance schemes for services provided at private hospitals. Any difference in the reimbursed amount and the fee for service would be paid out-of-pocket or through Appendix commercial insurance. Such a move would encourage greater use of private facilities and also boost demand for private insurance.

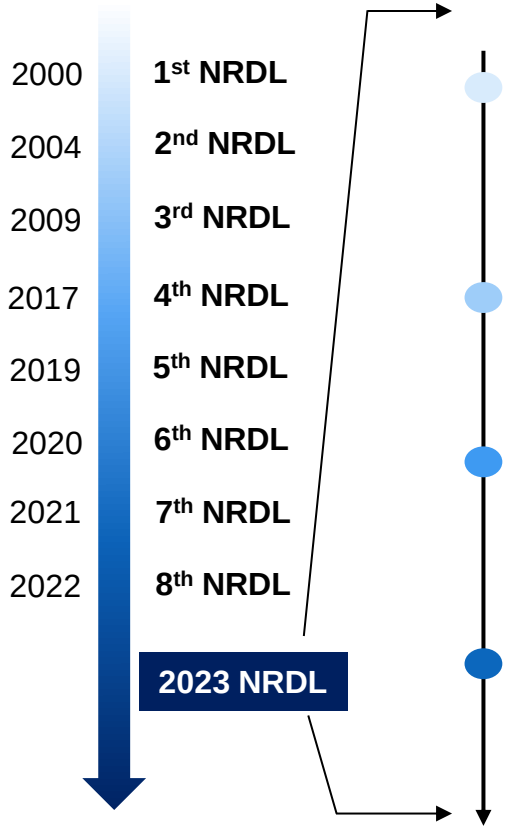
Source: NHFPC, Frost & Sullivan Analysis

Analysis of Healthcare Reimbursement System in China

Recent Progress and Impact of the 2023 NRDL

- In the 2023 NRDL, 126 drugs were newly included in the list, with a price reduction of 61.7%. The inclusion of numerous domestic innovative drugs has significantly promoted the sales of innovative drugs and the transformation of Chinese pharmaceutical industry to innovation.

Progression of NRDL



Recent Progression of 2023 NRDL

- In Dec 2023, NHSA and MOHRSS finished the work for the adjustment of the 2023 NRDL, and the 2023 NRDL will implement from Jan 1st 2024. The negotiation aims to eliminate medications with unreasonably high prices, optimize clinical use of medications, and further lower prices of current drugs by inducing virtuous competition.
- 143 kinds of drugs were involved in price negotiation, and 121 of them were smoothly negotiated. 126 kinds of drugs have been newly included in NRDL for the first time, leading to a 61.7% decline in prices.
- 1 previously included drugs were removed from the list, all of which are the varieties that have been cancelled by the NMPA.
- Anti-tumor drugs, rare disease drugs and anti-virus drugs have been newly included, such as Eggelstat, Siltuximab and Linperlisib, indicating the government is speeding up the review and approval of innovative drugs, urgently clinically needed drugs and rare disease treatment drugs.

Implication for Innovation

The inclusion of NRDL promoted the sales of innovative drugs significantly. At the same time, pharmaceutical companies need to embrace continuous innovation and accelerate the pace. Only those pharmaceutical companies that develop drugs with independent IP rights can win the industrial competition and keep a higher margin.

2023 NRDL restricts the price of drugs strictly by adding rules for non-exclusive drug bidding. If a drug is included in the list through bidding, the lowest price quoted by each enterprise shall be taken as the payment standard for the generic name drug.

Numerous domestic innovative drugs were included by 2023 NRDL, marking the initiation of a rapid increase of sales and the rapid transformation of the Chinese pharmaceutical industry towards innovation.

Since the implementation of the self-declaration system of pharma, only drugs that meet the conditions of 2023 NRDL plans can be included in the adjustment scope.

Source: MORHSS, Frost & Sullivan Analysis

Overview of Healthcare Insurance System in the US

Public Medical Insurance	**Medicaid**	• Medicaid is a medical and healthcare program for low-income groups. • Targeted at low-income parents, the elderly, children, and people with disabilities. • Jointly funded by the U.S. federal government and the state governments. • The CMS center supervises the implementation of the projects in each state.
	Medicare	• Established in accordance with the Social Security Amendment in 1965, which is operated by the US federal government. • It serves the elderly over the age of 65 or persons with disability or end-stage renal disease who meet certain conditions and are under the age of 65.
	CHIP(Children ‘s Health Insurance Program)	• Determined by the Balanced Budget Act of 1997, which provided health insurance for children from low- and middle-income families in the United States in the form of federal funding provided by the federal government. • The targets are those children whose family income is less than twice the federal poverty line and who have not participated in other private insurance.
Commercial Medical Insurance		• Commercial insurance providers are private insurance companies that contract with businesses or individuals to help cover healthcare costs according to criteria set forth in a formal health plan. Private health insurance plans typically require that the company or the individual receiving coverage pay a predetermined deductible or a monthly premium before benefits take effect. • Unlike heavy reliance on public medical insurance in China, commercial medical insurance contributes the majority of the healthcare services payment in US. Types of commercial medical insurance includes: 1. **Preferred provider organizations (PPOs):** PPOs operate off a list of preferred healthcare providers that patients can choose from for their coverage. Patients save the most money on their healthcare plans by selecting the preferred providers affiliated with a PPO. 2. **Health maintenance organizations (HMOs):** HMOs are groups of physicians, medical facilities, and healthcare services that work to keep patients under the care of providers within their network. Healthcare providers in HMOs coordinate a patient’s healthcare decisions and suggest a suitable hospital for urgent care. 3. **Point-of-service Plans:** Point-of-service plans form a hybrid between PPOs and HMOs. As with HMOs, point-of-service plans allow you to select physicians and services from within a dedicated network of providers.

Source: Frost & Sullivan Analysis

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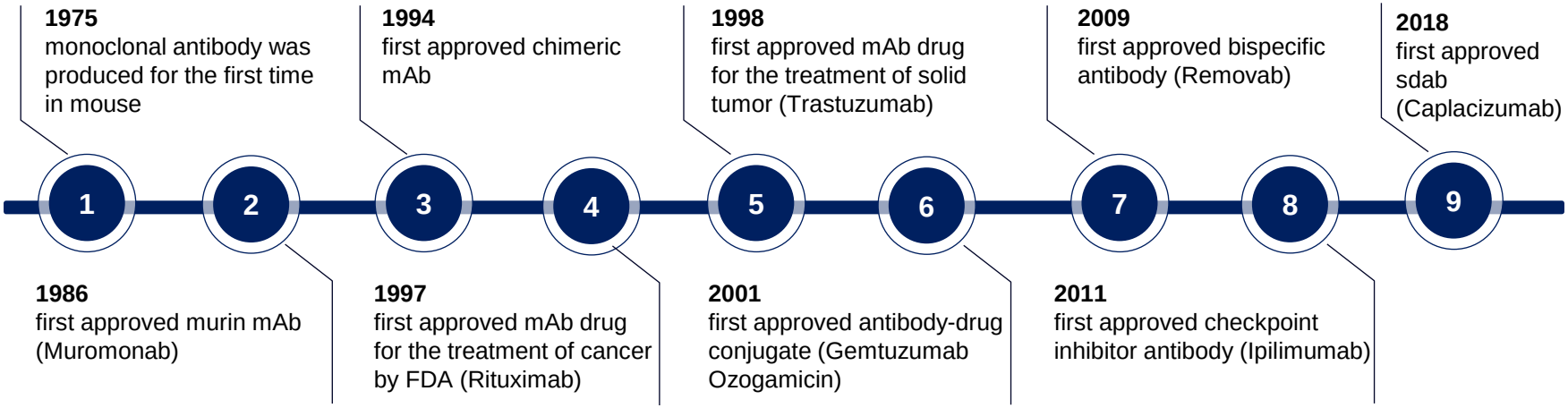
Analysis of Antibody Drug Development and Milestone Events

The Development History of Antibody Drug



The Key Development Trends

- **Increasing Safety Profile** Antibody drug development has experienced the murine antibody, chimeric antibody, humanized antibody, and now developed to fully human antibody, greatly improved the antibody drug safety by effectively reducing the immunogenicity and anti-drug antibody (ADA), which will cause corresponding side effect, fully human antibody has become the mainstream of the antibody drug development trend.

- **Improving efficacy** The efficacy of antibody drugs has been significantly improved through Fab affinity modification, Fc glycosylation and other antibody engineering technologies. At the same time, in recent years, antibody-conjugated drugs (ADC) that combine cytotoxic drugs, bispecific antibodies that can simultaneously target of two antigens, Single-domain antibodies with stronger affinity have also been developed to improve the efficacy of antibody drugs.

- **Expanding therapeutic area** With the continuous progress of antibody engineering technology and the discovery of more therapeutic targets, the therapeutic area of antibody drugs has been greatly expanded. It has expanded from the initial reducing acute rejection in patients with organ transplants to cancer, autoimmune diseases and ophthalmology, etc.

Source: Frost & Sullivan analysis

Classification and Comparative Analysis of Antibody Drugs

Comparison of Antibody Drugs and Chemical Drugs

- Compared to traditional chemical drugs, monoclonal antibodies are less available, more expensive and not fully covered by medical insurance. However, in terms of clinical value, antibodies have high specificity and high affinity for the corresponding antigens, making them unparalleled in the diagnosis and treatment of diseases, especially for the treatment of tumors.
- As the aging population in China and the morbidity and mortality rates of tumors continue to rise, patient demand for monoclonal antibodies will further increase, with huge market potential for antibody drugs for preventive vaccines, hormone deficiencies, molecular diagnostics and tumor therapy. At present, the international anti-tumor drug market is dominated by antibody drug. With the continuous development and depth of new technologies and antibody group drugs in the future, many new targets, new antibodies and antibody drug conjugation programs will be continuously developed and put into use, and antibody drugs with anti-tumor drugs as the core still have great development potential in the future.

Attributes	Antibody Drugs	Chemical Drugs
Category	Less diverse	A more comprehensive range
Price	High prices and few types of health insurance coverage	Lower prices and comprehensive health insurance coverage
Efficiency	Very high potency; very high specific affinity for antigens; high sensitivity; low dosage	Poor affinity for antigens; high dosing
Safety	Low side-effects; metabolized by the liver; kill only specific cells	High side effects; even on normal cells

Source: Frost & Sullivan Analysis

Classification and Comparative Analysis of Antibody Drugs

Overview of Antibody Drugs

Categories	Structure and Functions	Advantages	Limitations
Mono-antibody (mAb)	Mono-Antibodies that are made by identical immune cells that are all clones of a unique parent cell. mAb can have monovalent affinity, in that they bind to the same antigenic determinant.	Proven therapeutic effect for several kinds of diseases, especially for cancers and autoimmune diseases. High homogeneity. Possibility to produce large quantities of identical antibody.	mAbs diffuse poorly and large tumor masses may be more difficult to treat by mAb therapy. Triggering of ADCC by therapeutic antibodies faces several limitations, especially for low affinity variant of the receptor.
Bispecific antibody (BsAb)	A bispecific monoclonal antibody (BsMAb, BsAb) is an artificial protein that can simultaneously bind to two different types of antigen.	Potential used in various cancers, the application to retarget effector cells of the immune system and stimulate them through the interaction to achieve an efficient lysis of tumor cells.	Low expression of the target structures. Non-human nature, limiting the doses and the number of injections that can be given to patients. Difficulties in chemical, manufacturing and control (CMC) development.
Antibody-drug Conjugate (ADC)	ADC consists of antibody, linker and cytotoxin. The antibody can specifically target a specific antigen which is expressed in the tumor cells; the linker acts as a bridge for the ADC drug and is connected to the antibody by cleavable or non-cleavable linkers; the toxin small molecule should have high toxic activity and low immunity.	ADC drugs have larger tolerated doses, and smaller effective doses. ADCs are now also available in combination with other classes of drugs to enhance the effect of a single treatment. And ADC also targets non-oncology therapeutic areas, including imaging, CAR-T, etc.	ADC drugs may be off-target in the blood, resulting in the killing of normal cells. Antibody preparation cannot guarantee equal drug attachment for each antibody in each batch. Antigens are expressed only in tumor cells and not in normal cells.
Multi-Specific Antibodies	Multispecific antibody (msAb) is an artificial protein targeting two or more unique epitopes, which can bind more than one type of antigen.	Multi-specific antibody constructs potentiate antibody-mediated effects, via simultaneously blocking multiple tumor-associated antigens (TAA), and/or triggering more intensified immune reactions. Multiple functions translate into improved response rates.	Hetero-dimerization of chains may make the molecule inefficient. Potential antigenic cytokine release syndrome. Tight white cell binding may change bio-distribution. Large molecules have less intertumoral penetration and they are hard to be cleared with risk of aggregation.

Source: Frost & Sullivan analysis

Clinical Advantages of Antibody Drugs

- Monoclonal antibody only binds one epitope of target antigens, which could reduce the risk caused by cross reaction and drug side effects. Most patients only show a slight adverse effect during the monoclonal antibody therapy. Meanwhile the chance of getting systematic toxicity by monoclonal antibody is lower compared with chemotherapeutic drugs, due to its more concentrated therapeutic effect. With highly humanized monoclonal antibody the immunogenic response has been greatly reduced.
- In the trial of rituximab in the treatment of diffuse large B-cell lymphoma, the myelosuppression, gastrointestinal reactions, neurotoxicity, and hematological toxicity of the experimental group were significantly less than chemotherapy.

- As monoclonal antibody only targets and binds specific antigens, it could selectively kill target cells and exhibit a specific distribution in vivo for the treatment of cancer. This highly specific therapy provides more potent and concentrated efficacy.
  - Many mAb drugs have been proved to be very effective in the treatment of cancer. For instance, bevacizumab has been used in China for the treatment of non-small cell lung cancer in recent years and has become a first-line treatment option in the latest edition of the guidelines. Clinical trials have shown that bevacizumab combined with chemotherapy can significantly improve the objective remission rate of non-small cell lung cancer.

- Monoclonal antibody drugs possess a better tolerance compared with conventional chemotherapy and radiotherapy. During the treatment of monoclonal antibody, most of the common adverse effects are at low to middle level. Patients have a good tolerance and don't have to stop the treatment. For example, in the case of infusion of rituximab only less than1% patients had severe adverse effects and most patients could continue using this drug with a lower infusion rate after the symptoms disappeared.
- Monoclonal antibody has a long half time in vivo, so the frequency of administration could be reduced, which can reduce the psychological burden of patients and make them more acceptable to treatment.

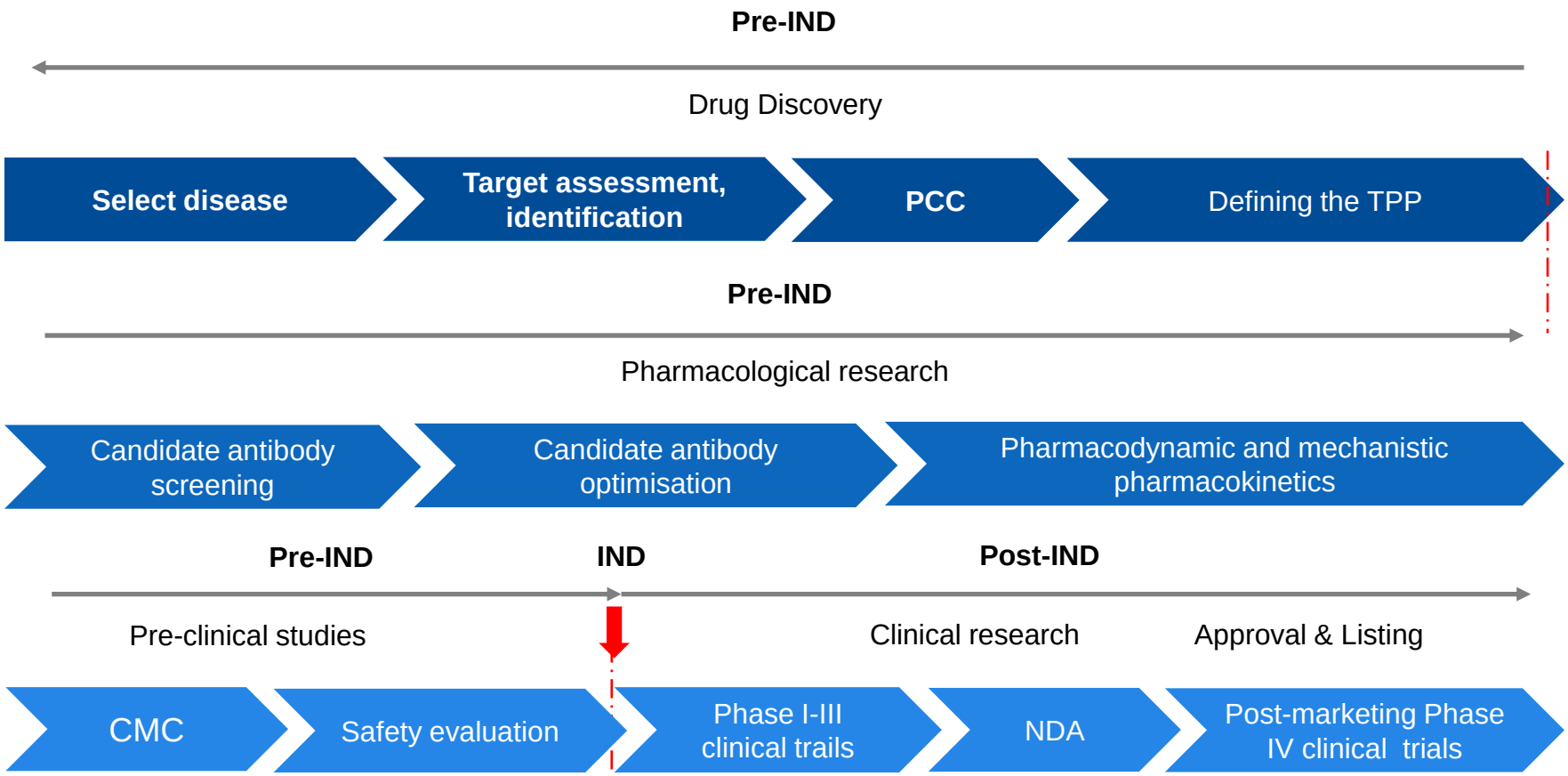
- The emergence of monoclonal antibodies has alleviated the lack of effective therapies in many cancers. The discovery of new monoclonal antibodies and new indications has increased the possibility of developing more therapeutic areas for monoclonal antibodies.

- Colorectal cancer is one of the most common malignant tumors of the digestive tract in China. It is the fourth most common type of cancer in China in 2018. Because of its low early diagnosis rate, traditional chemotherapy is often used in patients with advanced disease. The cetuximab approved by FDA in 2004 is important for the treatment of metastatic colorectal cancer with Kras/Nras/Braf wild type. In the CRSTAL study, median progression-free survival was significantly extended to 8.9 months in the patients treated with cetuximab, and the risk of disease progression was reduced by 15%.

Source: Frost & Sullivan analysis

Antibody Drugs Development Process Analysis

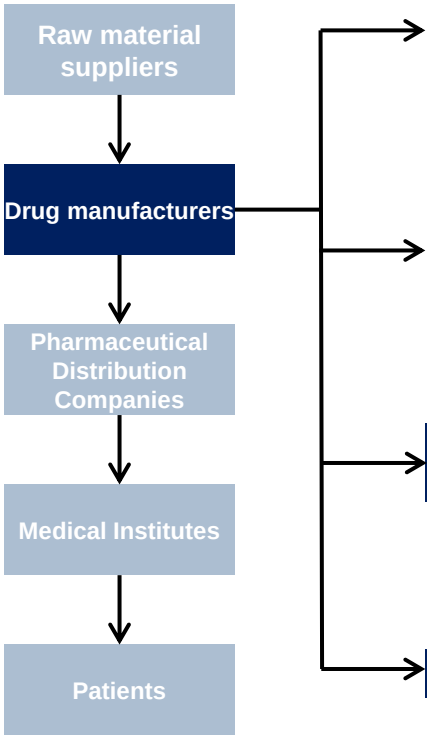
- The development of antibody drugs can usually be divided into three parts: from 0 to the discovery of pre-clinical candidate compounds; the validation process from PCC-IND (new drug clinical application) and the human clinical trial phase from IND-NDA (new drug application to market).



Source: Frost & Sullivan Analysis

Analysis of the Value Chain of Antibody Industry

- The upstream industry in antibody manufacturing is mainly raw material suppliers. The raw materials required for the production of antibodies include cell lines, culture medium, chromatographic media and so on. The quality of raw materials will directly affect the drug quality and fluctuations in their price will also affect the manufacturing costs of drugs.
- Pharmaceutical distribution companies and hospitals are downstream industries for mAb drugs. Hospitals provide patients with medical services and prescriptions of drugs and are main sales terminals while pharmaceutical distribution companies are responsible for the logistics such as cold chain and warehousing.



Drug discovery

The first step for monoclonal antibody development is to validate potential targets, which involve biophysics evaluation and cell- or tissue-based assessment. The following discovery procedures are involved with cell line construction, cell culture and purification, characterization of physicochemical and biological properties. Perfect and high efficient discovery process is dependent on high accurate and efficient analytic equipment. Meantime seeking a reasonable formulation in the pre-clinical experimental stage is beneficial for the development of subsequent clinical research.

Clinical Research

Persuasive clinical results are a key factor in drug approval. Review and approval by national regulators is a necessity for drugs to be marketed. The higher safety and effectiveness of drugs showed in clinical trials are also highly valuable for doctors and patients in selecting treatments. Therefore, screening for potential indications and patient populations is also one of the important considerations for clinical research.

Manufacturing Process

The manufacturing process of monoclonal antibody drugs is complicated, and its manufacturing cost accounts for a large proportion of total investment. Building large-scale production lines and improving cell culture processes are the main ways to increase productivity in the monoclonal antibody manufacturing industry. A well-developed technology platform can speed up the transition from pharmaceutical production to clinical use. However, while improving the productivity, we should try to avoid the adverse effects on the quality of the product due to unreasonable design in the production process to ensure the final quality of the drug.

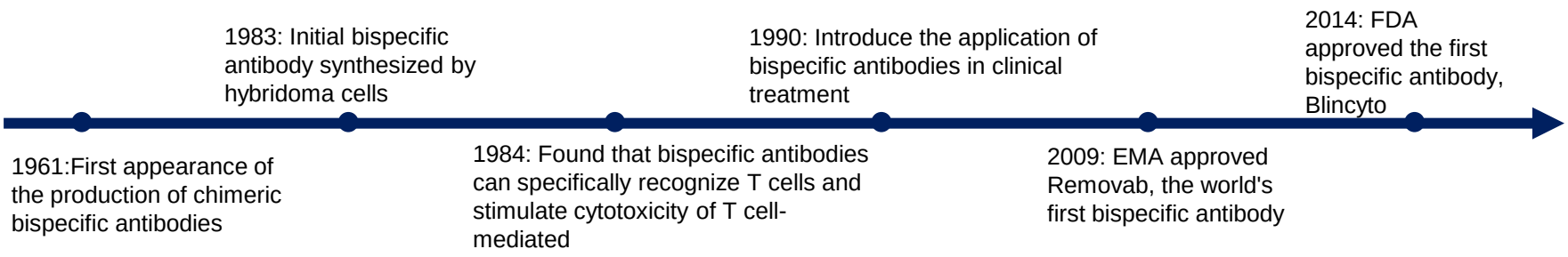
Commercialization

The downstream industry of monoclonal antibody drugs is mainly in the hospital drug market, which is the main distribution channel and trading place for monoclonal antibody drugs; patients can obtain drugs through doctor's prescription. However, the long payback period of the hospital will directly affect the cash flow of pharmaceutical companies. Due to the generally high price of monoclonal antibody drugs, it is necessary to focus on the patient's affordability and the coverage of medical insurance in the process of commercialization.

Source: Frost & Sullivan analysis

Analysis of the Development Process and Mechanism of Bispecific Antibody Drugs

- Bispecific antibodies can recognize and specifically bind to two antigens or epitopes of antigens. Theoretically, it can block the biological functions mediated by two antigens/epitopes at the same time or draw the two antigen cells closer, thereby enhancing their interaction.
- In recent years, with the in-depth understanding of the pathogenesis of various diseases and the development and progress of monoclonal antibodies, the development and progress of bispecific antibodies have been promoted. With the development of antibody construction, expression and purification technology, dozens of structures of bispecific antibodies have appeared. At present, tumor is one of the hot areas of double antibody research.



	Killing mediated immune cell	Blocking the proliferation signaling pathway	Dual target inhibition	Receptor co-stimulation or inhibition
Mechanism	It uses bridging effector T cells and tumor cells, and individually bridging NK cells. The antibody activates and relocates immune cells to promote the immune cells to kill the cancer cells.	Blocking the signal transduction pathways of growth factor receptors of tumor cells nad their downstream.	Acting on two different targets on cancer cells in order to inhibit compensatory or synergistic effects	Target two different receptors on immune cells, promote the activation of immune cells or block the suppression of immune cells
Example	• CD19+CD3 • EpCAM+CD3	• HER2+HER3 • IGF-1R+HER3	• VEGF+Ang-2 BsAb • EGFR+C-met	• PD-1 + CTLA-4 • PD-1 + LAG3

Source: Frost & Sullivan Analysis

Structural Classification of Bispecific Antibodies

- Currently, bispecific antibodies are generally divided into two categories according to their structure: IgG-type structure and non-IgG-type structure. Among them, the IgG structure can be divided into two types: symmetric and asymmetric, where the asymmetric structure has obvious advantages.

Non-IgG

Symmetric IgG

Asymmetric IgG

	Non-IgG	Symmetric IgG	Asymmetric IgG
Advantage	• Simple Structure • The clinical dosage is low, less than one-tenth of the original amount of antibodies • Weak immunogenicity	• Similar to the structure and stability of natural IgG • Mature technology, high expression	• Solved the technical limits of Knob-into-hole technology in common light chain • Realizes the bivalent binding of tumor antigens, which can reduce the toxicity caused by CD3 antibodies when binding to tumor antigens
Disadvantage	• Short half-life (only 2 hours) • Unstable structure, low expression and difficult process	• limited spatial bispecific binding effect	• Long technical route, difficult design and process
Marketed Examples	• Blinatumomab applies Tandem scFV and BiTE technology platform.Amgen is marketed in 2014, acute lymphocytic leukemia	PD-1 and CTLA-4 bispecific antibody Cadonilimab which listed in 2022	• Emicizumab applies KIH technology platform, marketed by Roche in 2017, hemophilia A • Catumaxomab applies Triomab asyme 1+1 (Rat-mouse hybrid IgG) platform, developed by TRION Pharma GmbH and Neovii Biotech GmbH in 2009 (withdrawn from the market in 2017), malignant pleural effusion

Source: Frontiers in Immunology, 2021: 1555., Analysis and Characterization of Antibody-based Therapeutics. Elsevier, 2020: 167-179., Journal of Immunology Research, 2019, 2019., Antibodies, 2018, 7(3): 28., Journal of hematology & oncology, 2015, 8(1): 1-14., Frost & Sullivan Analysis

Clinical Advantage of Bispecific Antibody

Compared with Mono Therapy

- **Mediate Immune Cell Killing towards Tumors:** BsAbs have two antigen-binding arms, one of which binds to the target antigen and the other binds to the labeled antigen on the effector T cell, which activates the effector T cell to kill tumor cells.
- **Stronger Specificity and Reduced Off-target Toxicity:** In contrast to mAbs, BsAbs interact with two different surface antigens respectively, which can effectively enhance the binding specificity and reduce side effects such as off-target.
- **Lower Drug Resistance:** Since one disease modulator may play an essential role in several independent pathways and co-expression of different receptors has been found in many tumors, targeting of two different growth-promoting receptors on a single tumor cell may increase the antiproliferative effect and help to avoid the development of resistance.

Compared with Combo Therapy

- **Reduce the Cost of Treatment:** In terms of dosage, since the therapeutic effect of BsAbs can reach 100-1000 folds of the common antibody, the lowest dose can be 1/2000 of the original, which significantly reduces the cost of drug treatment. The use of BsAbs compared to combination therapy with two monospecific drugs makes it possible to optimize expenses by reducing the cost of development and clinical trials.
- **Better Clinical-Doability:** Bispecific antibodies require only single administration compared to combo therapies that require multiple injections of two or more antibodies, simplifying the frequency and practice of administration, it shows great advantages in clinical trial development, clinical application as well as patient compliance.
- **Improved Safety:** In some clinical trials, the incidence of SAE of combo therapy of Nivolumab and Ipilimumab is higher than mon therapy, such as CheckMate 067. However, currently the early clinical trials have shown that PD-1/PD-L1 x CTLA-4 BsAbs has improved safety.

Source: Literature Review, Frost & Sullivan Analysis

Clinical Advantage of Bispecific Antibody

Advantages in Treating Retina Disorders

- Most treatments for retinal disorders target the VEGF(vascular endothelial growth factor), but not all patients respond to these treatments. BsAbs drugs target two pathways simultaneously, so patients who are not sensitive to anti-VEGF therapies might benefit from blocking the other angiogenesis pathway.
- Dual inhibition of Ang-2 and VEGF-A improves both structural and functional outcomes for patients with neovascular AMD and DME. When inhibiting Ang-2 in preclinical models, it seems to translate into a more robust VEGF-A inhibition effect. Manipulating both pathways simultaneously appears to be additive.
- BsAbs has better treatment durability and helps to reduce patients' injection frequency. Studies showed that more than 50% of patients were able to go 16 weeks or longer between treatments and more than 70% of patients were able to extend the treatment interval by 12 weeks or longer.

Advantages in Treating Hemophilia

- Hemophilia A is a bleeding disorder resulting from coagulation factor VIII (FVIII) deficiency. the common treatment for this disease is exogenously provided FVIII, which can reduce bleeding complications in patients with severe hemophilia A. However, approximately 30% of such patients develop inhibitory antibodies against FVIII (inhibitors), precluding FVIII treatment in this set of patients. Moreover, the poor pharmacokinetics of FVIII, attributed to low subcutaneous bioavailability and a short half-life of 0.5 d, necessitates frequent intravenous injections
- Bispecific antibodies for curing hemphilia like Emicizumab can recognize both the enzyme factor IXa and the substrate factor X. By simultaneously binding enzyme and substrate, BsAb drug could mimic some part of the function exerted by the original cofactor, FVIII, even in the presence of inhibitors.
- besides, bsabs have high subcutaneous bioavailability and a 2-week half-life and would not be expected to elicit the development of FVIII-specific inhibitory antibodies. Higher durability reduces the burden of care for the treatment of hemophilia A.

Source: Literature Review, Frost & Sullivan Analysis

Bi-specific Antibodies Approved by FDA

Marketed products globally

Product	Drug Name	Company	Target	Indications	Approval Time
BLINCYTO™	Blinatumomab	Amgen	CD3/CD19	Precursor B-cell Acute Lymphoblastic Leukemia (ALL), Refractory or Relapsed (R/R) ALL	12/2014
HEMLIBRA™	Emicizumab	Genentech	Fixa/FX	Hemophilia A	11/2017
RYBREVANT™	Amivantamab	Johnson & Johnson	EGFR/c-Met	Non-Small Cell Lung Cancer (NSCLC)	05/2021
VABYSMO™	Faricimab	Genentech	Ang-2/VEGFA	Neovascular (Wet) Age-related Macular Degeneration (AMD), Diabetic Macular Edema (DME)	01/2022
TECVAYLI	Teclistamab	Johnson & Johnson	BCMA, CD3	Malignant blood diseases	10/2022
LUNSUMIO	Mosunetuzumab	Genentech	CD20，CD3	Follicular lymphoma(FL)	12/2022
EPKINLY	Epcoritamab	Genmab	CD20，CD3	Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)	05/2023
COLUMVI	Glofitamab	Genentech	CD20，CD3	Diffuse Large B-Cell Lymphoma (DLBCL)	06/2023
TALVEY	Talquetamab	Johnson & Johnson	CD3,GPRC5D	Multiple Myeloma	08/2023
ELREXFIO	Elranatamab	Pfizer	BCMA,CD3	Multiple Myeloma	08/2023

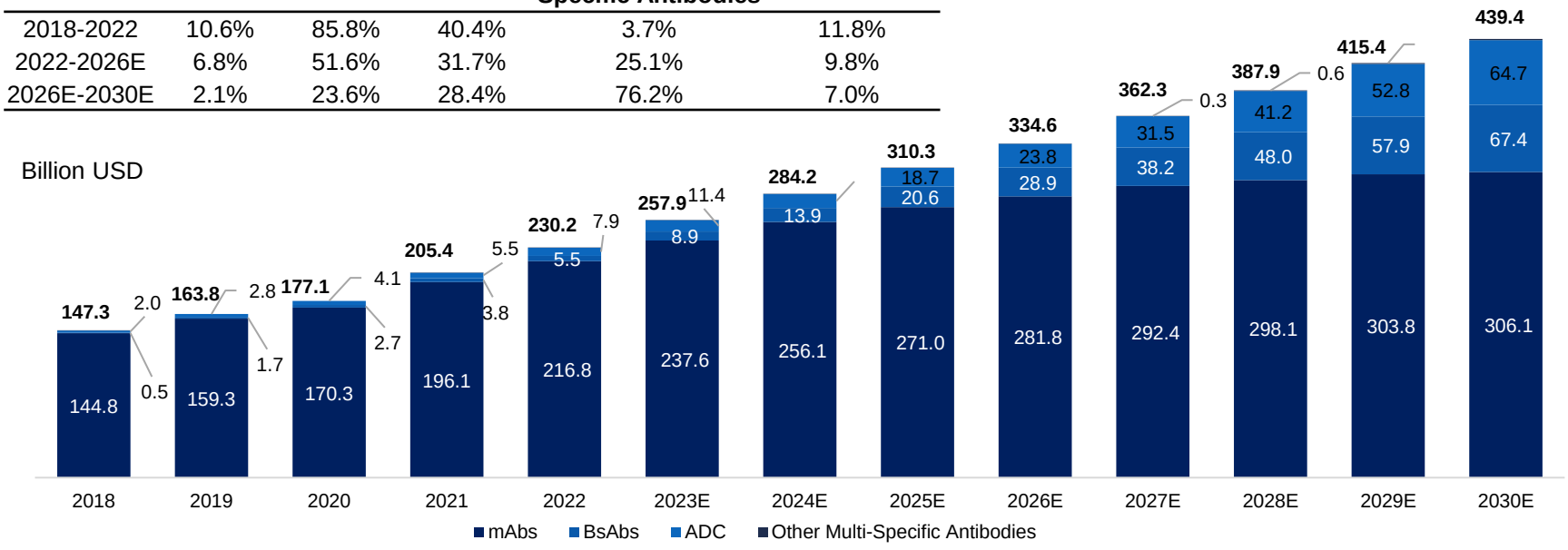
Source: FDA, Frost & Sullivan Analysis

Global Therapeutic Antibody Market Size and Forecast, 2018-2030E

- In 2022, global therapeutic antibody market grew to USD216.8 billion, with a CAGR of 11.8% from 2018 to 2022. The monospecific antibody is the largest category in global therapeutic monoclonal antibody market by revenue, and accounts for over 95% proportion. Though the bispecific antibody (BsAb), antibody-drug conjugates (ADC) and other antibody types, such as nanobody, are still in the initial stage of market, it is anticipated that the market of them will grow fast with the breakthrough of technology and clinical studies.
- In the next 10 years, global therapeutic antibody market will continue to grow to USD 281.8 billion in 2026 due to rising medical demand and innovative antibody pipelines, showing a CAGR of 9.8% from 2022 to 2026. Global therapeutic antibody market size will further to reach USD306.1 billion in 2030.

Historical and Forecasted Global Therapeutic Antibody Market Size, 2018-2030E

CAGR	mAbs	BsAbs	ADC	Other Multi-Specific Antibodies	Total
2018-2022	10.6%	85.8%	40.4%	3.7%	11.8%
2022-2026E	6.8%	51.6%	31.7%	25.1%	9.8%
2026E-2030E	2.1%	23.6%	28.4%	76.2%	7.0%



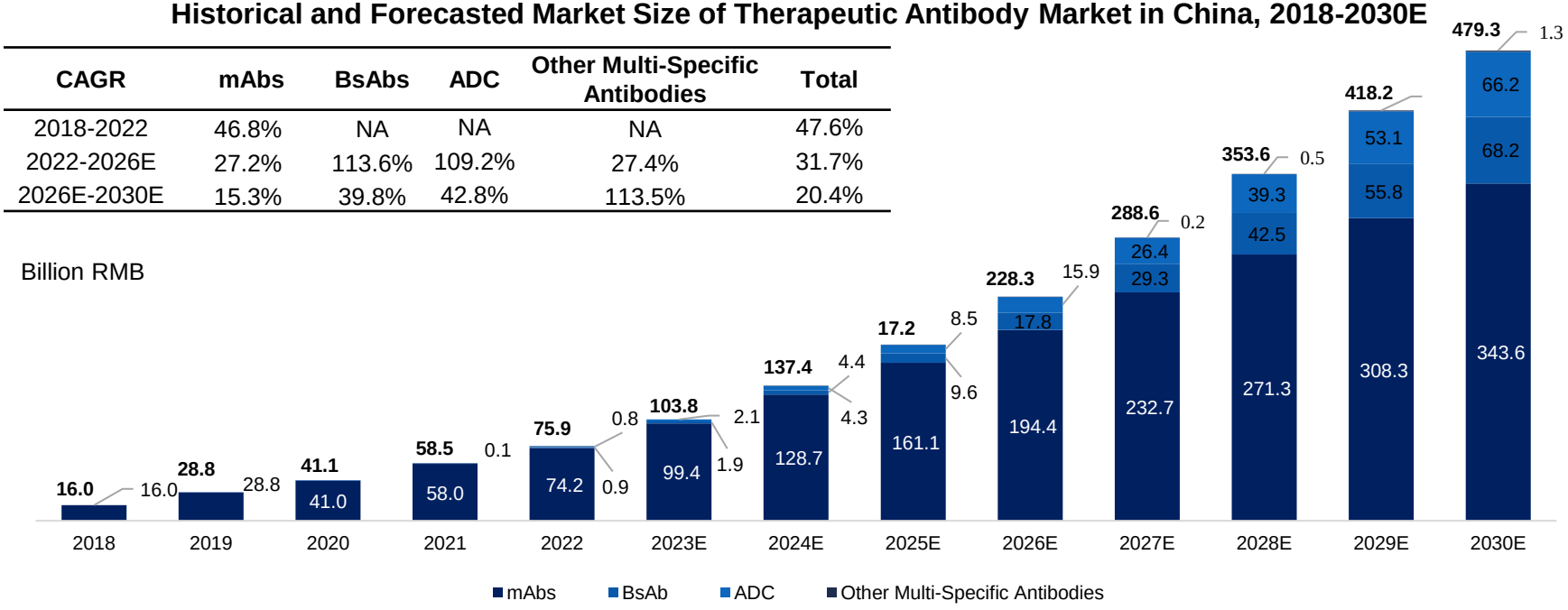
Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, FDA, IARC, GLOBOCAN, Frost & Sullivan Analysis

China Therapeutic Antibody Market Size and Forecast, 2018-2030E

- In 2022, China therapeutic monoclonal antibody market grew to RMB 75.9 billion, with a CAGR of 47.6% from 2018 to 2022. The monoclonal antibody will remain the largest category in China therapeutic monoclonal antibody market. However, there is also sufficient pipelines of BsAb and ADCs, as well as others innovative antibody types, such as HcAb and multi-specific antibody, under development. It is anticipated that the market of those innovative antibody drugs will grow fast with the breakthrough of technology and clinical studies.
- In the next 10 years, with more antibody drugs included in NRDL and increasing biosimilar availability as well as innovative antibodies launch in China, the domestic therapeutic antibody market will continue to grow to RMB 228.3 billion in 2026, showing a CAGR of 31.7% from 2022 to 2026, and the market size will further to reach RMB 479.3 billion in 2030.

Historical and Forecasted Market Size of Therapeutic Antibody Market in China, 2018-2030E

CAGR	mAbs	BsAbs	ADC	Other Multi-Specific Antibodies	Total
2018-2022	46.8%	NA	NA	NA	47.6%
2022-2026E	27.2%	113.6%	109.2%	27.4%	31.7%
2026E-2030E	15.3%	39.8%	42.8%	113.5%	20.4%



Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, NCCR, Frost & Sullivan Analysis

Growth Drivers of Antibody Drugs Market

Growing Needs of Domestic Antibody Drugs Market	• China's antibody drug industry has a huge room for development. In the face of the huge market demand, the production of antibody drugs will be a huge opportunity and challenge, and it is of great economic and social importance to develop new antibody drugs, optimize the production process of antibody drugs to increase the yield and reduce the production cost of antibody drugs. • Although bispecific antibody drugs have not yet achieved significant market share in the Chinese market, their development potential is huge. The market size of biclonal antibody drugs in China is expected to grow rapidly to 12.1 billion RMB by 2025, with a CAGR of 160.95% from 2021 to 2025.
Progressive Increase in Antibody Drug Financing	• The biopharmaceutical industry has been listed as a strategic emerging industry in China during the 12th Five-Year Plan period. In recent years, China has established the "National Engineering Center for Antibody Drugs" (Shang Hai), "State Key Laboratory for Antibody Drug Development" (Shi Jia Zhuang) and other national key laboratories. The industry has also formed its own internal industry " Antibody Industry Alliance" and other organizations. The market demand drive, industrial policy support, all for China's antibody industry development provides a good opportunity.
Leading Domestic Company's Entering the Ranks of BsAbs R&D	• The representative domestic enterprises include Baji Shenzhou (Beijing) Biotechnology Company Limited, Xinda Biopharmaceutical Company Limited, Shang Hai Hai Mai Biotechnology Company Limited, Suzhou Kangning Jere Biotechnology Company Limited, Pumis Biotechnology (Zhuhai) Company Limited, Wuhan Youzhi You Biopharmaceutical Company Limited, etc. Due to the strong investment of these pharmaceutical giants, the clinical trials of bispecific antibody drugs have surged, although many of them are in pre-clinical stage, but with the continuous promotion of clinical trials of these products, the future development potential of dual anti-drug track is huge.
High Market Conversion Rate	• Compared to other types of drugs, antibody drugs have a high market conversion rate, and indications are gradually expanding to other disease areas. In terms of the conversion rate of antibody drugs at various stages, clinical phase I has the highest success rate. The current global utilization of antibody capacity is increasing and clinical capacity is also increasing.
High Return Rate	• The high price of antibody drugs guarantees a very high rate of return. In recent years, the national bioengineering and monoclonal antibody drugs have shown rapid development from R&D pipeline to market sales performance. Guided by the concept of high investment, high output and high return, major domestic pharmaceutical companies have increased their investment efforts.

Source: Frost & Sullivan analysis

Future Trends of Antibody Drugs Market

Development of New Targets/ Therapies	• In comparison with mAbs marketed abroad, the mAbs have relatively a shorter history in China with less approved drugs. Therefore the mAbs available in China cover fewer indications. Under this circumstance there are extensive unmet clinical demands. With the acceleration of R&D and approval process mAbs will cover more therapeutic areas that are currently not met, including cardiovascular, ophthalmology, nervous system, etc. Novel therapies including bispecific antibody (BsAb), heavy chain antibody (HCAb), single-chain variable fragment (ScFV), single-domain antibody (sdAb), etc..
Increase of Penetration	• Previously the permeability of mAbs in patients was quite low due to its expensive price and not being included in NRDL. Since 2017 the amount of mAbs that have been approved and included in NRDL has increased dramatically, greatly increasing the accessibility of drugs to patients. At the same time, the launch of biosimilars has driven the continued growth of the entire biopharmaceutical market, increasing the accessibility of mAbs to patients. As emergence of biosimilars has also reduced the cost of patients, the affordability and accessibility of the mAbs will increase its permeability simultaneously.
Diversity of Antibody Drugs	• To reduce immunogenicity, the developing platforms of mAbs has undergone the process from murine to chimeric, humanized and fully human. With the rapid development of DNA recombination technology, major breakthroughs have been made in antibody screening, Fc engineering and other aspects. The diversity of antibodies has been greatly enriched, such as BsAb, HCAb and scFv. These diversified structure would be beneficial to suit respective functional needs. The development of antibodies is gradually developing towards humanization, functionalization, miniaturization, and specialization.
Value Creation Through Innovation	• Currently most of the share in Chines mAbs market is held by MNCs, domestic monoclonal antibody industry is still in its starting stage. As domestic companies are focusing on the research of similar targets and the expected targeted indication is close, these will intensity the commercial competition. • Innovative pipelines which have proven clinical value should distinguish companies in such a competition environment. Further, innovative mAbs have great opportunities to stand out in the mAbs market mainly based on the clinical value.
BsAbs Focus More on Solid Tumors	• There is real enthusiasm for the ongoing studies of BsAbs in solid tumors, which are supposed to yield promising results in the near future, although translating BsAbs into clinically applicable drugs may be time consuming and requires tremendous effort. With the biotechnology advance and new target identification, therapeutic bi-specific antibodies are a hot field for drug development.

Source: Frost & Sullivan analysis

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Development Path of Cancer Treatment

- Cancer treatment has gone through a long process of development in history, and it will continue to evolve over time with the innovative and hard work of scientists around the world.
- Today, major treatments include surgery, radiotherapy, chemotherapy, targeted therapy, and immunotherapy.

Milestones in Cancer Treatment

Surgery
1881, first successful surgery performed for stomach cancer

- ***Surgery*** is a procedure in which a surgeon removes cancer from patient's body.
- Surgery works best for solid tumors that are contained in one area. It is not used for leukemia or for cancers that have spread. Surgery may be performed before or after other forms of treatment.
- In addition to removal of the primary tumor, surgery is often necessary for staging.

Radiotherapy
1903, first successful use of radiation to cure skin cancer

- ***Radiotherapy*** is a cancer treatment that uses high doses of radiation to kill cancer cells and shrink tumors.
- Radiotherapy can be used to treat many types of cancer including solid tumors and leukemia. And in many cases, patients receive radiotherapy with other cancer treatments, such as surgery and chemotherapy.
- Radiation not only kills or slows the growth of cancer cells, it can also affect nearby healthy cells, which will cause side effects.

Chemotherapy
1949, FDA approved first chemotherapy drug - nitrogen mustard - for the treatment of Hodgkin lymphoma

- ***Chemotherapy*** is a cancer treatment that uses chemical substances, especially one or more anti-cancer drugs to stop or slow the growth of cancer cells.
- Chemotherapy can be used to treat many types of cancer alone or in combination with other treatments.
- Chemotherapy also causes side effects such as mouth sores, nausea, and hair loss.
- Typical chemotherapeutic drugs include alkylating agents, antimetabolites, anti-tumor antibiotics and etc..

Targeted Therapy, Immunotherapy
2014, FDA approves the first bi-specific antibody drug, Blinatumomab

- ***Targeted therapies*** act on specific targets that are associated with cancer growth, thus they do less harm to normal cells. Most targeted therapies are either small-molecule drugs or monoclonal antibodies.
- ***Immunotherapy*** Immunotherapy includes cellular Immunotherapy, cytokines, antibody-like drug, oncolytic virus, fusion proteins.
- Antibody-like drugs include monoclonal antibody, bispecific antibody, antibody conjugate drug (ADC) and multi-specific antibodies.

Source: Literature Review, Frost & Sullivan Analysis

Oncology Treatment Evolvement

Primary Treatment

1. Surgery

- Cancer surgery removes the tumor and nearby tissue during an operation. Best for early stage tumors that are contained in one area but is limited for cancers that have metastasized.

2. Radiotherapy

- High doses of radiation to kill cancer cells and shrink tumors including solid tumors and leukemia.
- Affects nearby healthy cells, causing side effects such as fatigue, hair loss and skin changes.

3. Chemotherapy

- Uses one or more anti-cancer drugs to stop or slow the growth of cancer cells.
- Targets all fast growing cells, causing side effects such fatigue, hair loss, easy bruising and bleeding, and infection.

4. Targeted Therapy

- Act on specific targets that are associated with cancer growth
- Less harmful to normal cells than traditional therapies
- Include both small molecule drugs and monoclonal antibodies

Treatment Evolution

5. Immuno-Oncology Therapy

Immunotherapy includes cellular Immunotherapy, cytokines, antibody-like drug, oncolytic virus, fusion proteins.
Antibody-like drugs include monoclonal antibody, bispecific antibody, antibody conjugate drug (ADC) and multi-specific antibodies.

Significant Evolution

- The use of chemotherapy to treat cancer began in the early 20th century. in the 1960s and early 1970s, combination chemotherapy showed efficacy in curing acute leukemia in children and advanced Hodgkin's disease, overcoming the pessimism that prevailed at the time about the ability of drugs to cure advanced cancer and promoting research in adjuvant chemotherapy. Today, important molecular mutations are often used to screen for potential new drugs as well as targeted therapies, and remain the cornerstone of anticancer drug therapy for many cancer patients.
- While monoclonal antibodies have become the backbone of cancer therapy, bispecific antibodies in immunotherapy are emerging as an important and promising component of the next generation of therapeutic antibodies due to their ability to simultaneously target two epitopes in the tumor cell or tumor microenvironment.

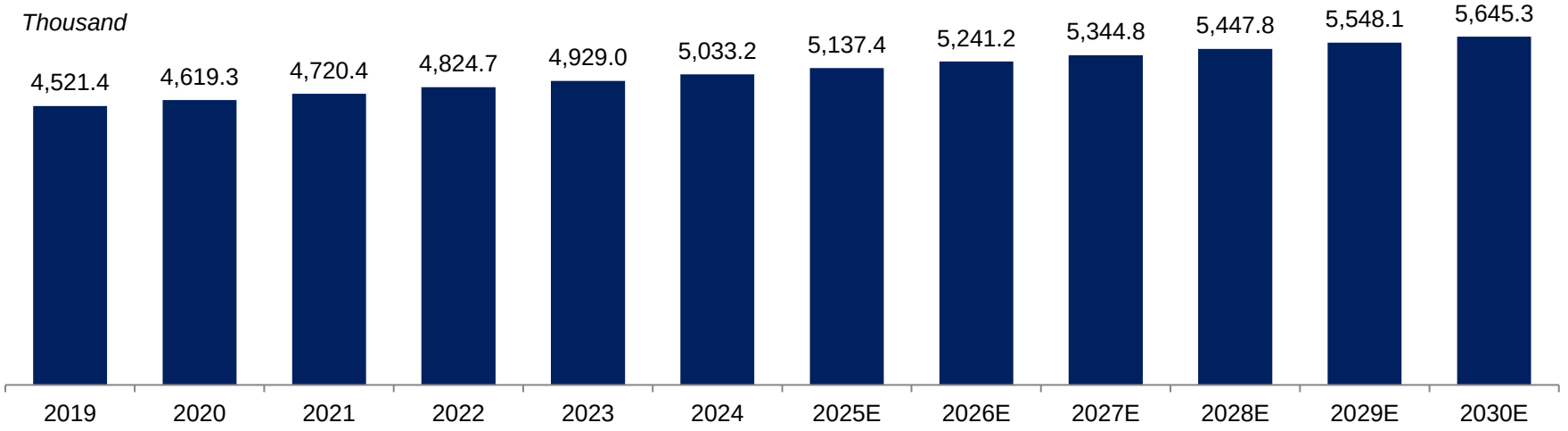
Source: Literature Review, Frost & Sullivan Analysis

China Cancer Incidence, 2019-2030E

- In China, cancer incidence number reached 5033.2 thousand in 2024 at a CAGR of 2.7% from 2019. It is projected to further increase to 5,241.2 thousand in 2026, representing a CAGR of 1.4% from 2023. It is estimated that the number would achieve 5,645.3 thousand in 2030, representing a CAGR of 1.9% from 2026 to 2030.

China Cancer Incidence, 2019-2030E

Period	CAGR
2019-2024	2.7%
2024-2026E	1.4%
2026E-2030E	1.9%



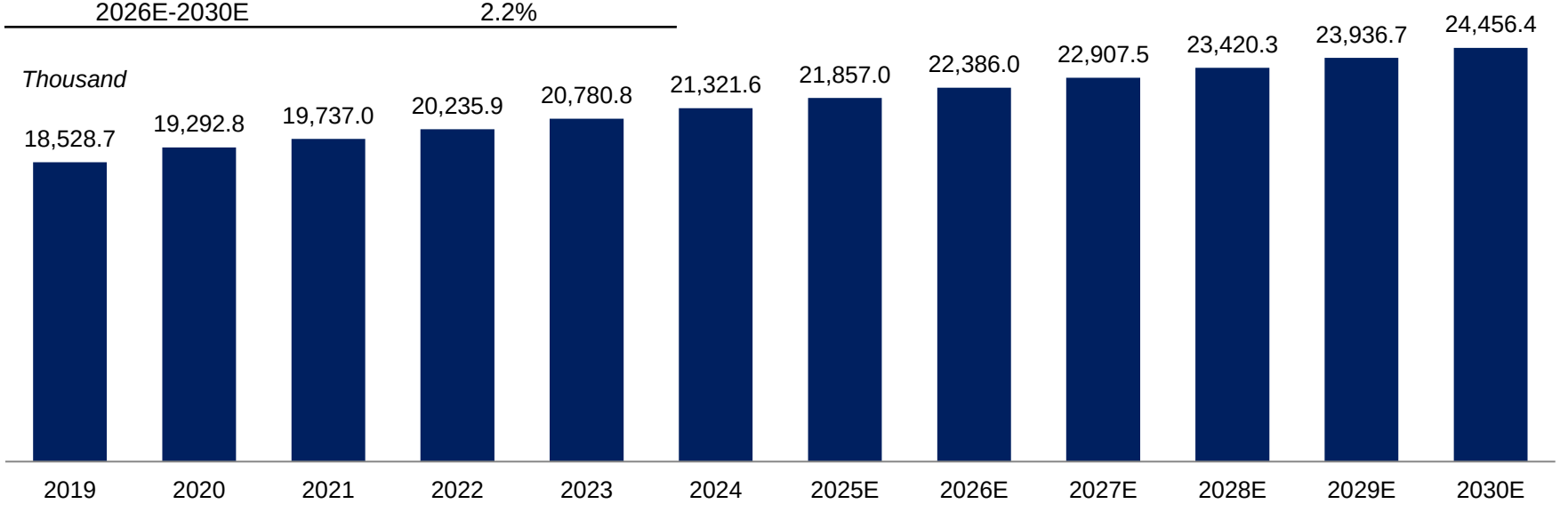
Source: NCCR, Frost & Sullivan Analysis

Global Cancer Incidence, 2019-2030E

- In global, cancer incidence number reached 21,321.6 thousand in 2024 at a CAGR of 2.9% from 2019. It is projected to further increase to 22,386.0 thousand in 2026, representing a CAGR of 1.6% from 2023. It is estimated that the number would achieve 24,456.4 thousand in 2030, representing a CAGR of 2.2% from 2026 to 2030.

Global Cancer Incidence, 2019-2030E

Period	CAGR
2019-2024	2.9%
2024-2026E	1.6%
2026E-2030E	2.2%



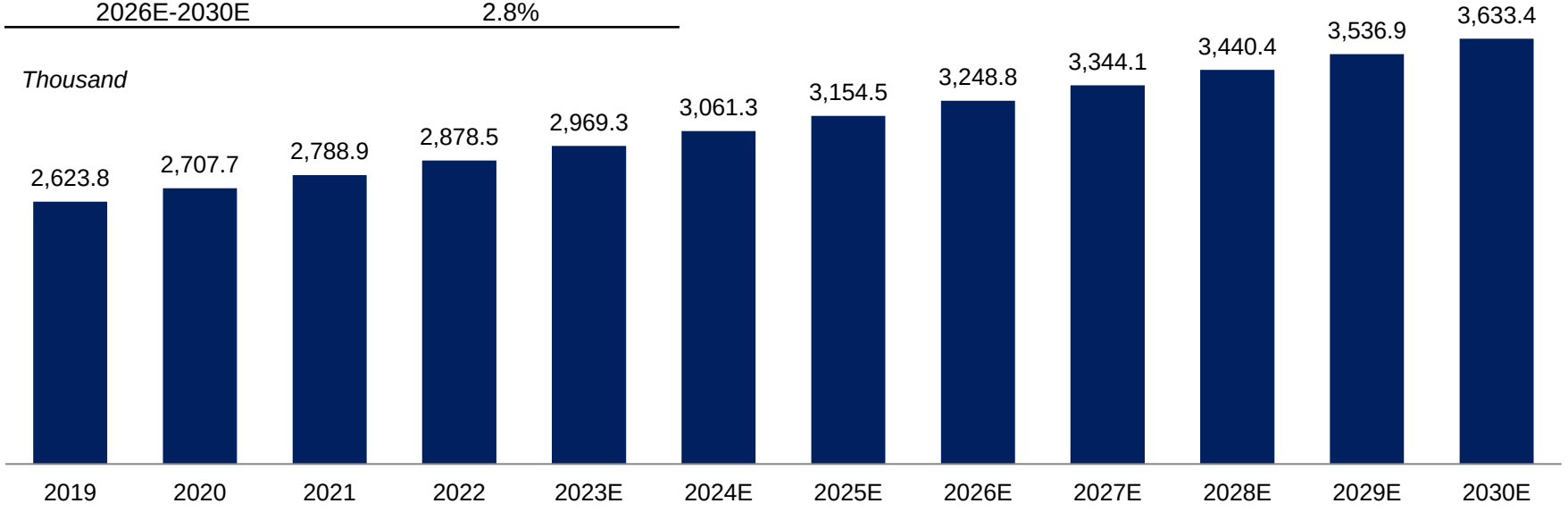
Source: IARC, Frost & Sullivan Analysis

China Cancer Mortality, 2019-2030E

- In China, cancer mortality reached 2,878.5 thousand in 2022 at a CAGR of 3.1% from 2019. It is projected to further increase to 3,248.8 thousand in 2026, representing a CAGR of 3.1% from 2022. It is estimated that the mortality would achieve 3,633.4 thousand in 2030, representing a CAGR of 2.8% from 2026 to 2030.

Cancer Mortality in China, 2019-2030E

Period	CAGR
2019-2022	3.1%
2022-2026E	3.1%
2026E-2030E	2.8%



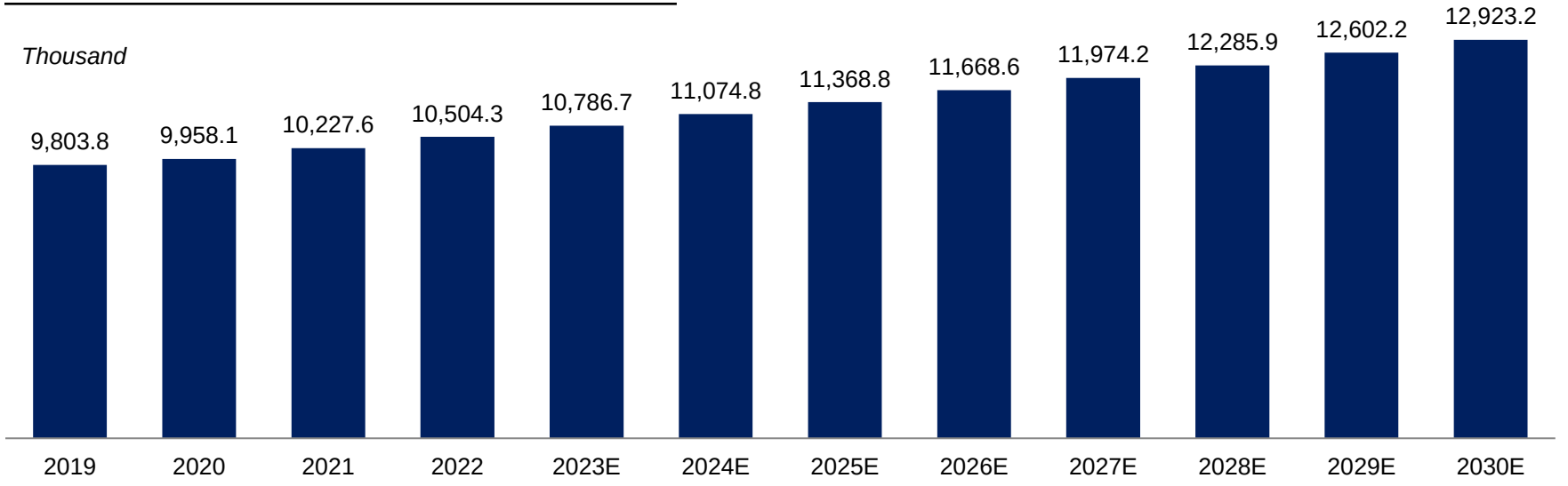
Source: NCCR, Frost & Sullivan Analysis

Global Cancer Mortality, 2019-2030E

- In global, cancer mortality reached 10,504.3 thousand in 2022 at a CAGR of 2.3% from 2019. It is projected to further increase to 11,668.6 thousand in 2026, representing a CAGR of 2.7% from 2022. It is estimated that the incidence would achieve 12,923.2 thousand in 2030, representing a CAGR of 2.6% from 2026 to 2030.

Global Cancer Mortality, 2019-2030E

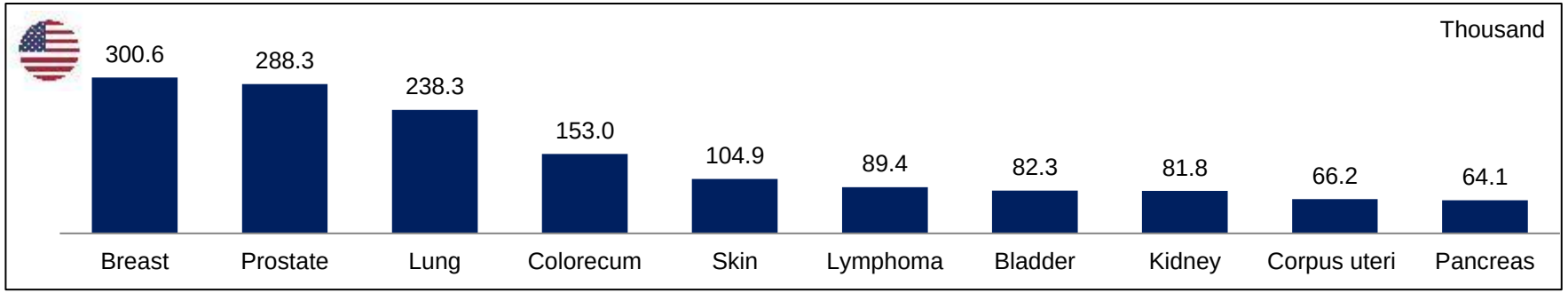
Period	CAGR
2019-2022	2.3%
2022-2026E	2.7%
2026E-2030E	2.6%

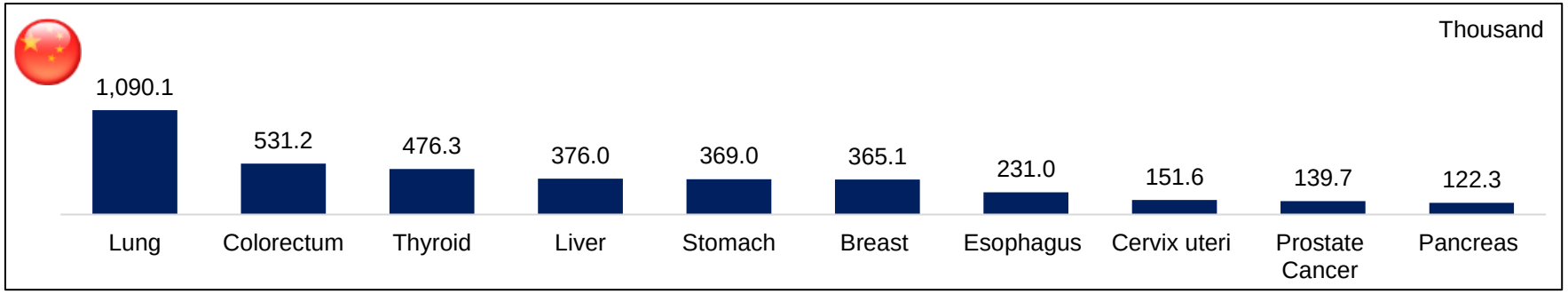


Source: IARC, Frost & Sullivan Analysis

Top 10 Cancers by Incidence in 2023, US VS China

- The USA and China have demonstrated different structures of Top 10 cancers in terms of new cases in 2023.
- Breast cancer has the largest number of patients in the USA, while lung cancer threatened the lives of the most cancers patients in the China.

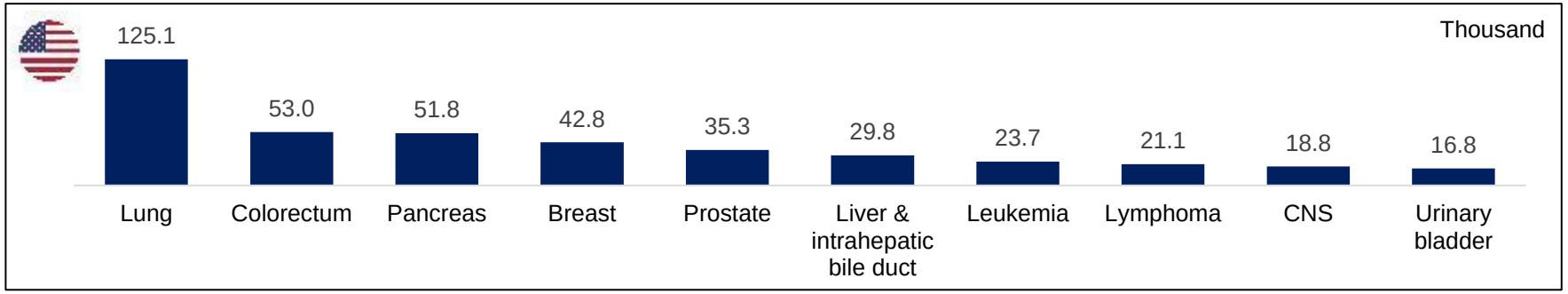


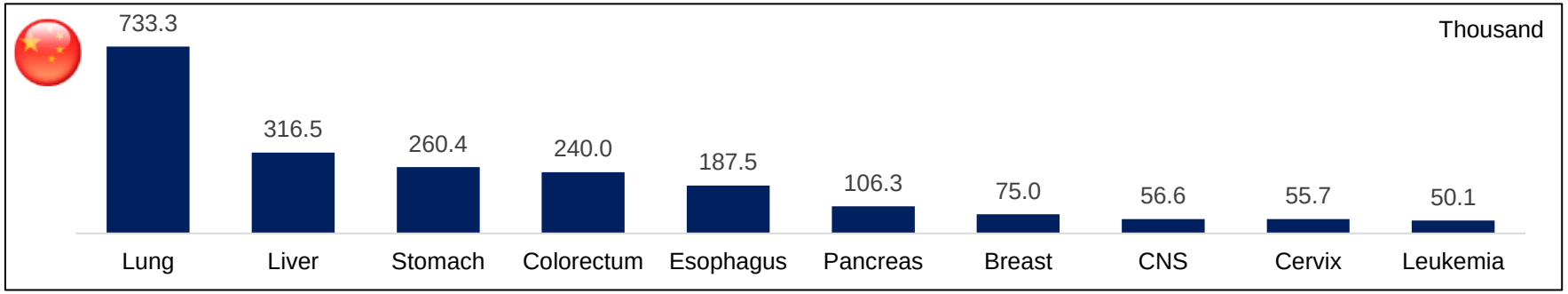


Source: NCCR, ACS, Frost & Sullivan Analysis

Top 10 Cancers by Mortality, US 2023 VS China 2022

- The mortality of lung cancer ranks the highest in the USA. Colorectum is the second most fatal in the global., whereas it ranks the fifth in China. Liver cancer is the second most mortal cancer in China.

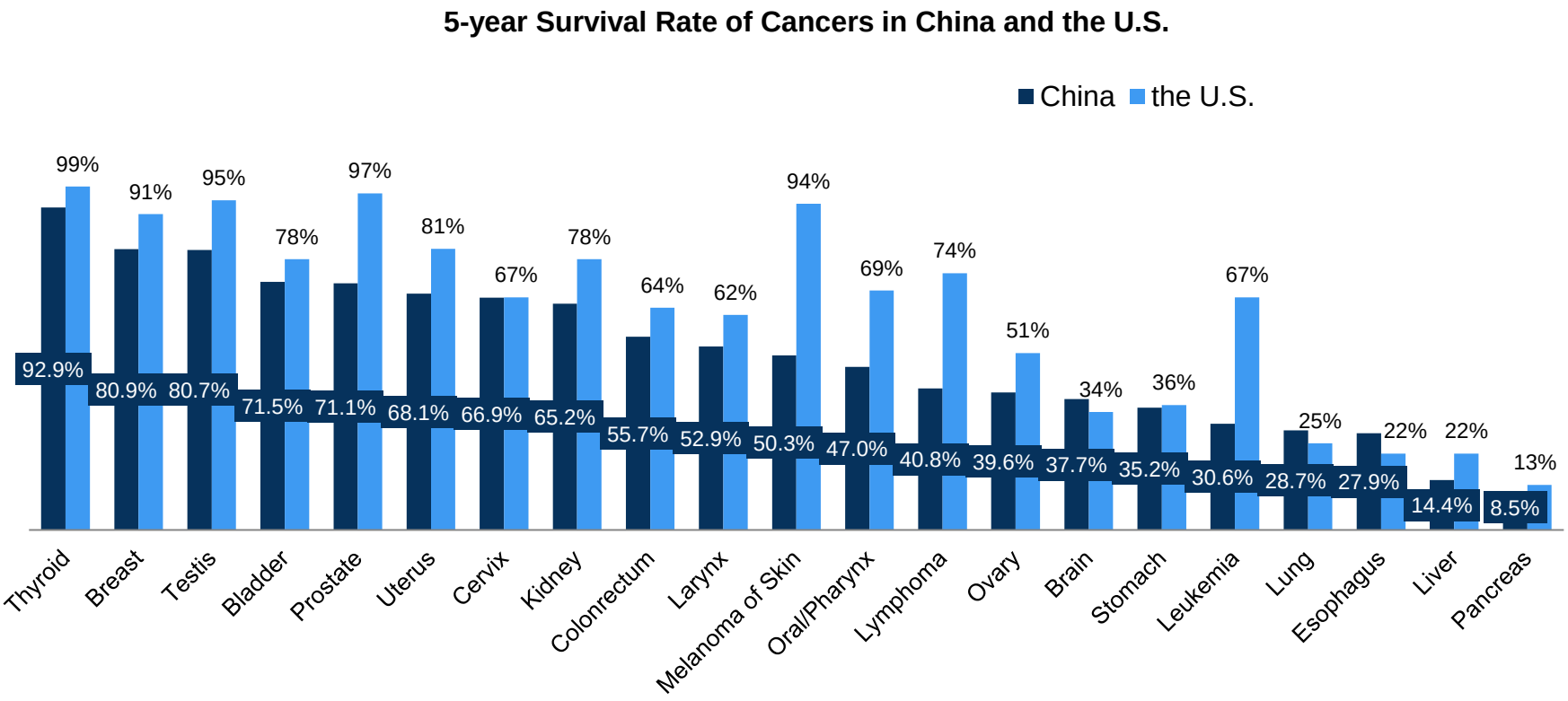




Source: NCCR, ACS, Frost & Sullivan Analysis

Comparison of 5-year Survival Rate of Cancers in China (2019-2021) and in the U.S. (2013-2019)

- China's 5-year survival rate lags far behind the U.S. in melanoma of skin, lymphoma and leukemia.
- The overall 5-year survival rate in China and in the U.S. are 43.7% and 69% respectively.



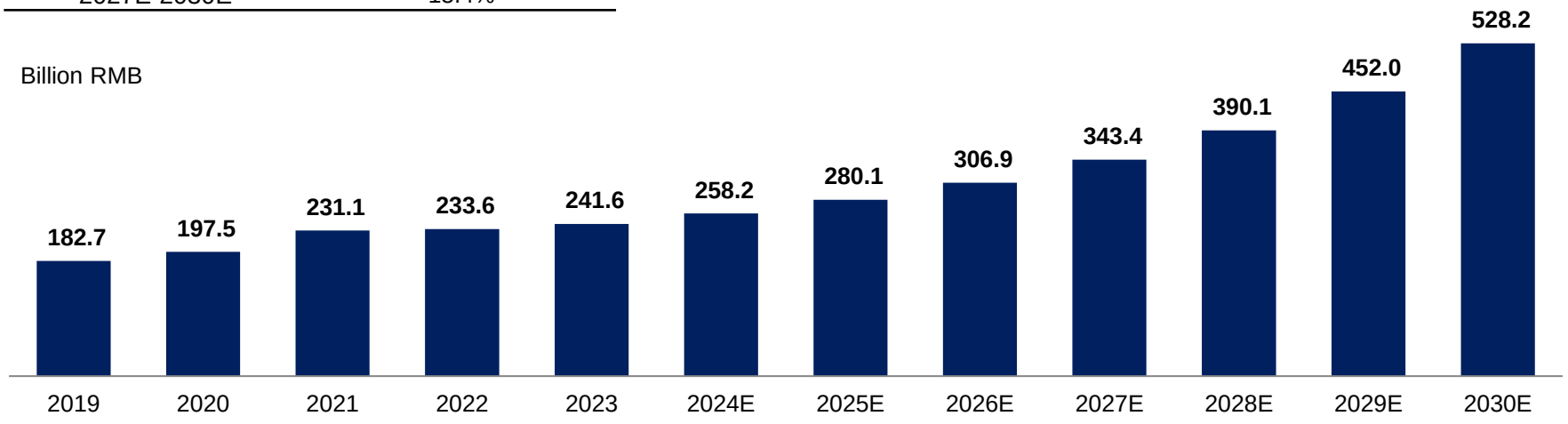
Source: NCCR, ACS, Frost & Sullivan Analysis

China Oncology Drug Market, 2019-2030E

- In Chinese drug market, sales of oncology products has risen steadily in the recent years. China oncology market, generating RMB258.2 billion in 2024, experienced a CAGR of 7.2% over the past 5 years.
- The ever-changing of successful innovative oncology treatments have promised a high return of pharmaceutical manufacturers. China oncology market is expected to uptrend in the following years. From 2024 to 2027, China oncology market is going to reach RMB343.4 billion at wholesale price level with CAGR of 10.0%. Forecasted data shows that China oncology market would be RMB548.4 billion in 2030, representing a CAGR of 15.4% from 2027 to 2030.
- While competition in China's oncology drug market is fierce, companies with in-house capabilities throughout the entire value chain of oncology drug development, including drug discovery, process development, clinical development, quality control and assurance and commercialization, are better positioned to capture the growth potential of this market.

China Oncology Drug Market, 2019-2030E

Period	CAGR
2019-2024	7.2%
2024-2027E	10.0%
2027E-2030E	15.4%



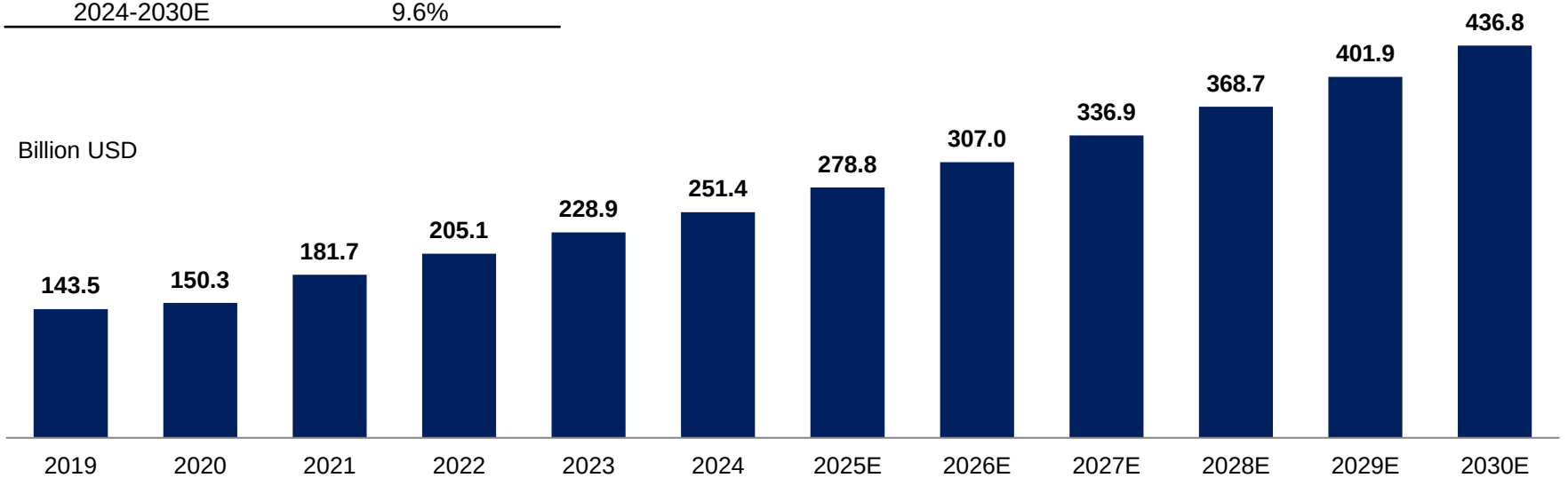
Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, NCCR, Frost & Sullivan Analysis

Global Oncology Drug Market, 2019-2030E

- From 2019 to 2023, global market of cancer drugs expanded from USD143.5 billion to USD228.9 billion, representing a CAGR of 12.4% during this period. The steadily growing market results from the expanding patient pool and increasing affordability of healthcare service.
- Global oncology market is expected to garner USD305.8 billion by 2026, with a CAGR of 10.1% during the forecasted period from 2023 to 2026. Immunotherapies/ biologics are emerging as potential therapies to get the permanent cure for various cancer types. Amongst various biologics, drugs based on monoclonal antibodies (mAbs) have gained significant attention in recent years and would further propel the growth of oncology/cancer drugs market due to their high efficacy.
- Global oncology market is expected to generate USD419.8 billion revenue by 2030, with an annual growth rate of 8.2% from 2026 to 2030.

Global Oncology Drug Market, 2019-2030E

Period	CAGR
2019-2024	11.9%
2024-2030E	9.6%



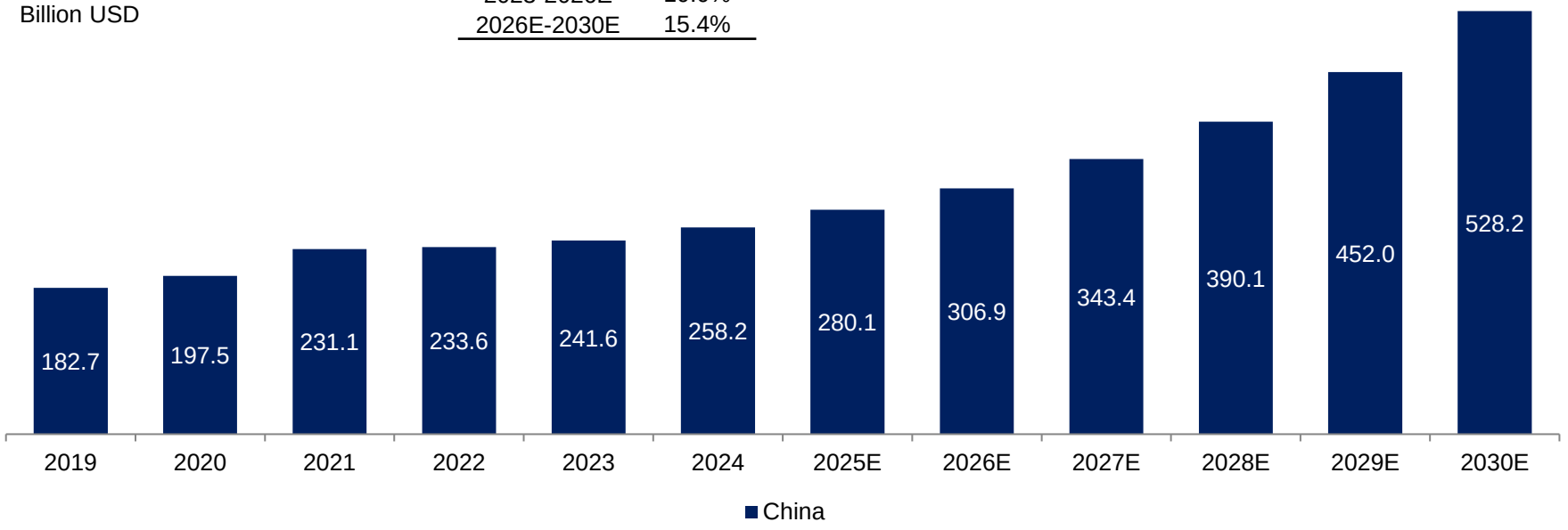
Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, FDA, IARC, GLOBOCAN, Frost & Sullivan Analysis

Global Oncology Drug Market by Region, 2019-2030E

- The size of global oncology drug market was USD 228.9 billion in 2023, and is expected to reach USD 305.8 billion and USD 419.8 billion in 2026 and 2030 respectively, representing a CAGR of 10.1% from 2023 to 2026 and 8.2% from 2026 to 2030. The size of China oncology drug market was USD 34.1 billion in 2023, and is expected to reach USD 49.9 billion and USD 77.5 billion in 2026 and 2030 respectively, representing a CAGR of 13.5% from 2023 to 2026 and 11.6% from 2026 to 2030. The size of US oncology drug market was USD 105.0 billion in 2023, and is expected to reach USD 149.1 billion and USD 209.9 billion in 2026 and 2030 respectively, representing a CAGR of 12.4% from 2023 to 2026 and 8.9% from 2026 to 2030.

Global Oncology Drug Market by Region, 2019-2030E

Period	CAGR
	China
2019-2023	7.2%
2023-2026E	10.0%
2026E-2030E	15.4%



Source: IARC, Frost & Sullivan Analysis

Growth Drivers of Oncology Drug Market

Increasing Cancer Incidence	• Global cancer incidence grew over past years, and it is expected that it to grow in the future. The total cancer incidence has reached 20.7 million globally in 2023, and is expected to further increase to 22.3 million in 2026. The increase of cancer incidence can be attribute to increasing lifespan, more aging population, and obesity. The high incidence create a demand for oncology drugs that will drive the growth of oncology drug market.
Improving Affordability	• According to WHO, nearly 1 in 6 death worldwide is due to cancer, and approximately 70% of those deaths occur in low- and middle-income countries. Managing cancer is complicated by increasing prices and insufficient benefits for patients and public health of new medicine coming to market. Thus, an improved affordability of patient is a key in pushing oncology drug market forward by alleviating the burden of cancer treatment. In many countries, the cancer reimbursement system is getting more mature, for example. Medicare Program in US and NRDL dynamic reimbursement list in China have both made efforts in realizing cancer patient reimbursement.
Investigation on Innovative Targeted Drugs	• With a deeper understanding on cancer, it is revealed that even patients with the same type of cancer exhibit different genotype or different expression level of certain proteins that are key in tumor formation pathway. These proteins can potentially serve as tumor prognostic biomarkers. Intensive researches have been done in some of the previously oriented tumor related targets, which reveals a potential of treating a wide patient population with different tumor features. Such investigations has demonstrated the importance of potential new targets that have in fulfilling unmet need of patient subgroups. Thus, the more innovative targets identified and applied in drug development, the more clinical need will be addressed, and the further the oncology market expansion.
Technology Advancement	• Technology advancement brings revolution to the pharmaceutical R&D and manufacturing process, enabling the advent of targeted therapy, immuno-oncology therapy etc. to address the unmet clinical needs. Patients suffering from cancers have benefited from improving 5-year survival rate. The demand of oncology drugs has significantly been driven up. With the further R&D investment and efforts, more novel therapies will be launched and further prolong the survival of cancer patients. Market is expected to further go up with increasing clinical demand.
Rising Small and Mid-sized Pharmas	• Small and mid-sized pharmas which can offer potentially more promising career opportunities are attractive for sales and R&D talents trained at MNCs. With engagement by talents attrition from MNCs, R&D activities are no longer dominated by MNCs. Small and mid-sized pharmas concentrate more on specialty drugs like oncology and are more flexible in operation, injecting vitality to the oncology drug industry.

Source: Frost & Sullivan Analysis

Future Trends of Oncology Drug Market

Precision Cancer Treatment	• Oncology market is promoting precision treatment. In order to provide precision treatment to different subtypes of patients, targeted cancer therapy emerges and develops rapidly, which involves drugs or other substances to block the growth and spread of cancer by interfering with those specific molecular targets. With the continuous exploration on innovative targeted drugs, precision treatment of cancer will be applied to a wider tumor-related targets, making it a future trend. For example, in China, besides a previous hot fad of exploring targets such as EGFR, VEGFR and CD20, oncology drugs targeting CD47, NKG2A, HLA, CSF-1R, etc. are being investigated more recently, urging the precision treatment of related cancer.
Inclusion of more Oncology Drugs in NRDL	• The establishment of National Healthcare Security Administration promotes the rapid progress of medical insurance, including the NRDL revision by price negotiation and dynamic adjustment, through which oncology drugs can be included in the reimbursement list in a more flexible manner, benefiting the potential patients by expanding the anti tumor drugs on the list. For example, since the dynamic implementation, 17, 18, 23, 21 oncology drugs (including chemical and biological drugs) were included in the 2020-to-2023 NRDL.
Development of Innovative Immunotherapies	• In the past few decades, immunotherapy has revolutionized cancer treatment and rejuvenated the field of tumor immunology. However, Most of the immunomodulatory approaches currently being developed engage the adaptive immune system and there are still some deficiencies with current immunotherapies, such as respond rate issues associated with PD-1/PD-L1 therapy. With the increasing significant progress in understanding the molecular basis of the immune response to cancer as well as the basic mechanisms of cellular immunology, innovative immunotherapies such as immunocytokines and innate immunotherapies will gradually emerge, thereby offering an alternative immunotherapeutic option.
Managing Cancer as a Chronic Disease	• Newer treatments extend survival and active treatment time frames. Furthermore, patients unable to take current cancer therapies or who have developed resistance to initial therapies may be able to take advantage of new options and lines of therapy, resulting longer lifespan. • With the availability of oncology drugs and awareness of health management, cancer is expected to have longer 5-year survival rate, becoming a kind of chronic disease like diabetes and hypertension and making cancer requires more than treatment but also follow-up and rehabilitation after treatment, which develops an increasing demand for more advanced screening methods, such as gene sequencing and imaging detection, and rehabilitation solutions, such as special nutritional support, cachexia treatment and comorbidity treatment.

Source: Frost & Sullivan Analysis

Overview of Immune Cells

- Immunes cells are important components of the immune system that widely participates in immunologic functions such as scavenging dead, dying body cells; system destroying abnormal/cancerous cells, protecting the body from pathogens and foreign molecules.
- Innate immunity is non-specific, while adaptive immunity target specific antigens. Macrophage, NK cell and dendritic cell are major immune cells of innate immunity, while T lymphocytes (T cell) and B lymphocytes (B cell) that of adaptive immunity.

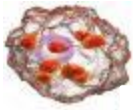
Innate Immunity

◆ Respond to a broad range of foreign substances in a common way, acts very quickly.

Dendritic cell (DC)

Distribution:
Widely distributed in all organs except brain in human.
Function:
Phagocytosis and antigen presentation.

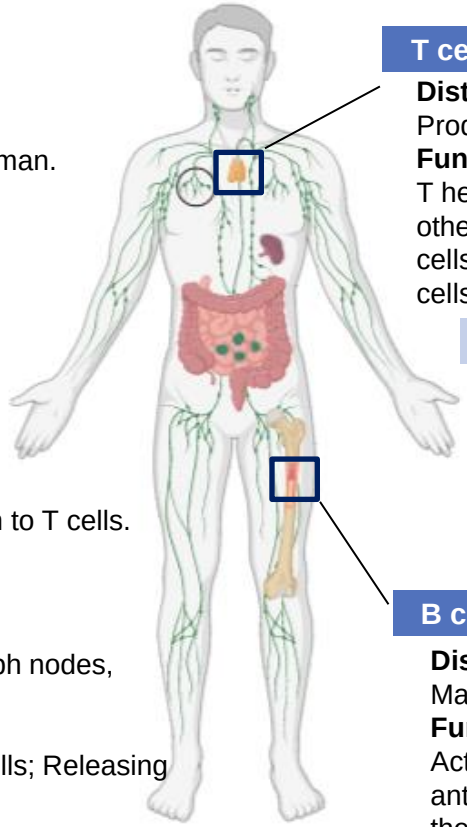
Macrophage



Distribution:
Derived from bone marrow stem cells and enter the bloodstream and distribute in various organs and tissues.
Function:
ADCC/ADCP; Phagocytosis; Antigen presentation to T cells.

Nature Killer (NK) cell

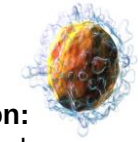
Distribution:
Present in most organs (bone marrow, lungs, lymph nodes, peripheral blood, spleen and liver etc.).
Function:
ADCC; Tumor rejection; Destruction of infected cells; Releasing perforin and granzymes which induce apoptosis.



Adaptive Immunity

◆ Identify and target specific antigen, response slower but more accurate.

T cell



Distribution:
Produced in bone marrow and matured in the thymus.
Function:
T helper cells use chemical messengers to activate other immune system cells, some become memory T cells after the infection has been defeated; Cytotoxic T cells detect and destroy infected cells.

Antibody

Distribution:
Produced by the B lymphocytes and circulate in the bloodstream
Function:
Activate other immune cells; Activate system immune response proteins.

B cell

Distribution:
Made in the bone marrow and then mature.
Function:
Activated and transform into plasma cells, producing antibodies and release them into the blood. Some of the activated B cells transform into memory cells.

Note：*Antibody does not belong to adaptive immune cells, but it is an important immune active substance secreted by B cells.

Source: Literature Review, Frost & Sullivan Analysis

Overview of the Immune System

- The immune system is a network of immune molecules, cells, tissues, organ and biological processes that function to protect the body from potentially harmful foreign substances such as microbes (organisms such as bacteria, fungi, and parasites), viruses, cancer cells, and toxins.
- By the nature of defense mechanism, the immunes system can be divided into two categories: innate immunity and adaptive immunity. The two subcategories are not mutually exclusive, but complementary to each other.

Categories of Immune System

Innate Immunity

Description: pre-exisiting, non-specific defense mechanism that is used by host body to fight against foreign molecules, and has no immunologic memory

Major Components:
- Physical barriers: skin, mucous membrane, etc
- Innate immune cells: phagocytes (dendritic cells, macrophages, neutrophils), natural killer cells, etc
- Immune molecules: cytokines, complements, lysozyme, etc

Adaptive Immunity

Description: antigen-dependent, specific defense mechanism that mechanism that a body develop to fight against foreign molecules, with immunological memory created

Major Components:
- Adaptive immune cells: B cells, T cells
- Immune molecules: immunoglobulins (Igs, e.g. antibodies), T cell receptors, major histocompatibility complex (MHC), etc

Source: Literature Review, Frost & Sullivan Analysis

Overview of Innate and Adaptive Immune System

- Generally, the human immune system can be divided into the innate immune system and the adaptive immune system. The innate immune system forms the body's first line of defense and consists of proteins and cells that identify foreign cells and provide an immediate response, such as phagocytosis. Innate immune cells include macrophages, natural killer cells (NK cell) and dendritic cells (DC). The adaptive immune system, including T cells and B cells, functions as the second line of defense that identifies and eliminates specifically presented pathogens.

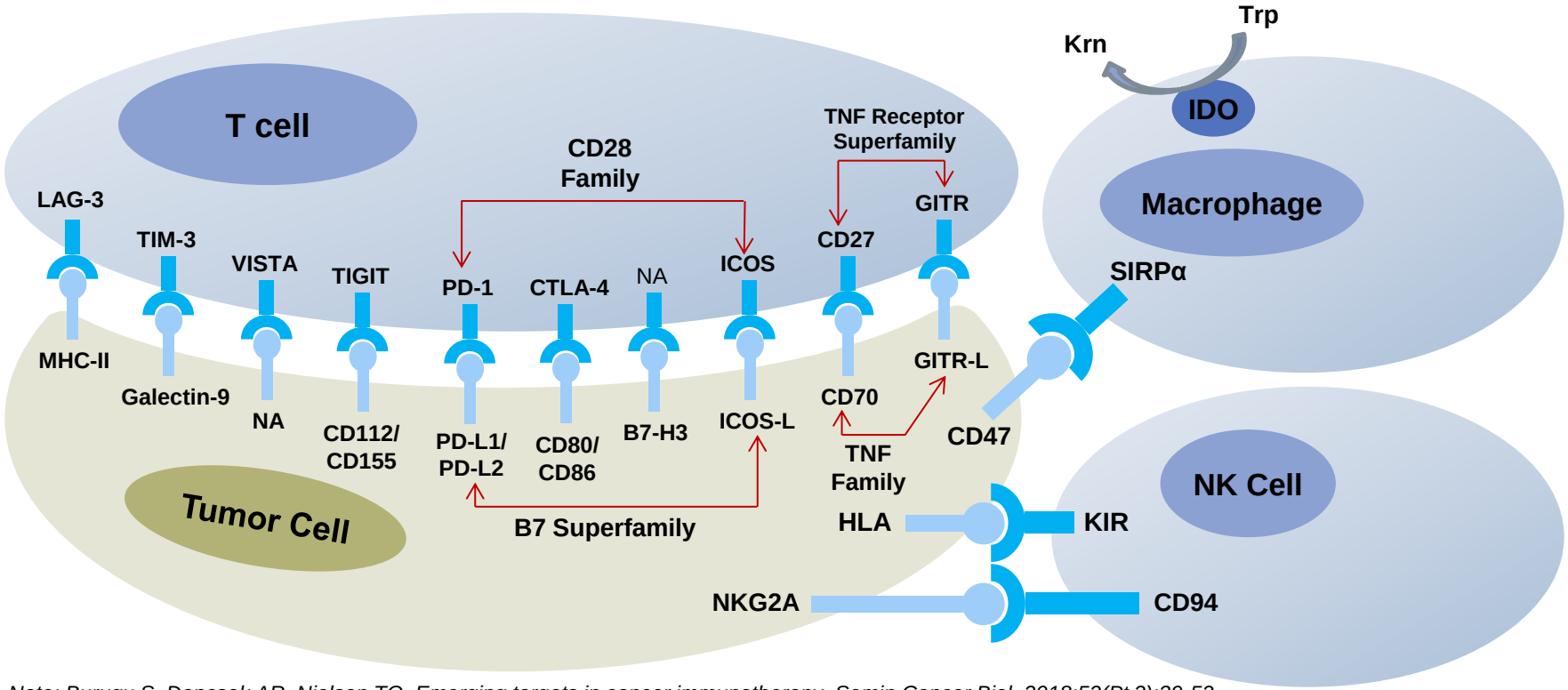
	Activation Process	Key Immune Cell Type	Tumor Tissue Distribution	Major Immune Checkpoint(s)	Major Immune Functions
Adaptive Immunity	Antigen priming required	T cell	10-30%	PD-1/PD-L1, CTLA-4, LAG-3, TIM-3, TIGIT	T-cell mediated killing of tumor cell via exocytosis of cytotoxic granules (perforin, granzymes) and secretion of antitumor cytokines
		B cell	3%-40%	CD40/CD40L, CD19, CD22	• Antibody production • Cytokine secretion
Innate Immunity	First line of defense, short response time, no need for antigen priming	Macrophage	20-50%	CD47/SIRPα, CD24/Siglec-10, PSGL-1, EP4	• Macrophage-mediated phagocytosis • Attracting T cells to the tumor microenvironment (TME) • Antigen presentation • Trogocytosis
		NK cell	5%-10%	KIR and NCR family, CD94-NKG2A, CD24/Siglec-10, TIGIT, EP4	• NK cell-mediated cytolysis via the secretion of perforin and granzymes • Activating of T cells, macrophages and DCs through release of cytokines
		DC	3%-10%	PD-1/PD-L1, CD47/SIRPα, EP4	• Attracting T cells to the TME • Antigen presentation

Note: The tumor tissue distribution is the proportion of certain immune cells in different tumor tissues. NA refers to no clear studies about the tissue distribution rate of NK cell and DC.

Source: Literature Review, Frost & Sullivan Analysis

Overview of Cancer Immuno-Oncology Therapy

- Over the last few years, immuno-oncology therapy has revolutionized cancer care. Immuno-oncology therapy is designed to stimulate the patient's own immune system to generate or augment an antitumor immune response in order to control or eradicate cancer cells. Due to its ability to provide durable remissions while being generally well-tolerated in certain patients with advanced cancers, the discovery and development of immuno-oncology therapy in recent years mark a milestone in cancer treatment.
- Innate immunity and adaptive immunity are two types of immunity. Intrinsic immunity, which is present from birth, enables a rapid response to various invading pathogenic microorganisms and also plays an important role in the process of initiation and effect of specific immunity. Adaptive immunity involves specialized immune cells and antibodies that attack and destroy foreign invaders and are able to prevent disease in the future by remembering what those substances look like and mounting a new immune response.



Note: Burugu S, Dancsok AR, Nielsen TO. Emerging targets in cancer immunotherapy. Semin Cancer Biol. 2018;52(Pt 2):39-52.

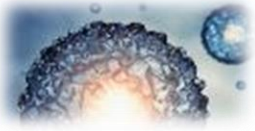
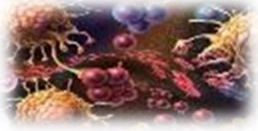
Source: Literature Review, Frost & Sullivan Analysis

Classification of Immuno-Oncology Therapy

By Nature of the Products

- Immuno-Oncology therapy is an emerging pillar of cancer treatment, alongside with surgery, chemotherapy and radiation, inducing parts of human's immune system to fight diseases. The process can be down in either stimulating immune system to attack cancer cells or giving immune system components. According to the market caliber, the products of Immuno-Oncology therapy are mainly divided into cellular Immunotherapy, cytokines, antibody-like drug, oncolytic virus, fusion proteins and etc. Antibody-like drugs (generalized as the term antibody) include monoclonal antibody, bispecific antibody, antibody conjugate drug (ADC). Fusion proteins refers to proteins created through the joining of two or more genes that originally coded for separate proteins. Antibody-like drugs and fusion proteins are better developed and they can achieve the aim of multi-target immuno-oncology therapy.

Immuno-Oncology Therapy

Cellular Immunotherapy	Cytokines	Antibody-like Drug	Fusion Protein	Oncolytic Virus
				
Genetically Modified: CAR T (Kymriah®, Yescarta®), TCR-T **Non-genetically Modified:** AAL (Immuncell-LCTM, EAL®) CIK, NK, LAK, DC, TIL	**IL-2:** Ontak®, Proleukin® **IFN:** Multiferon® Pegasys®	**Monoclonal antibody (mAb):** Opdivo® **Bispecific antibody:** blinatumomab® **Antibody conjugate drug (ADC):** Kadcyla®	**Bispecific fusion protein** Tebentafusp **Fc fusion protein** Eylea ® ARCALYST ®	**Adenovirus:** Oncorine® **Echovirus:** Rigvir® **Herpes virus:** Imlygic® **Herpes simplex virus type 1:** Delytact®

Source: Frost & Sullivan Analysis

Classification of Immuno-Oncology Therapy

By Target and Mechanism

- Immuno-Oncology therapy is an emerging pillar of cancer treatment, alongside with surgery, chemotherapy and radiation, inducing parts of human's immune system to fight diseases. The process can be down in either stimulating immune system to attack cancer cells or giving immune system components. The target and mechanism of immuno-oncology therapy compromises innate immune system, adaptive immune system, tumor microenvironment & cytokines and cellular immunotherapy.

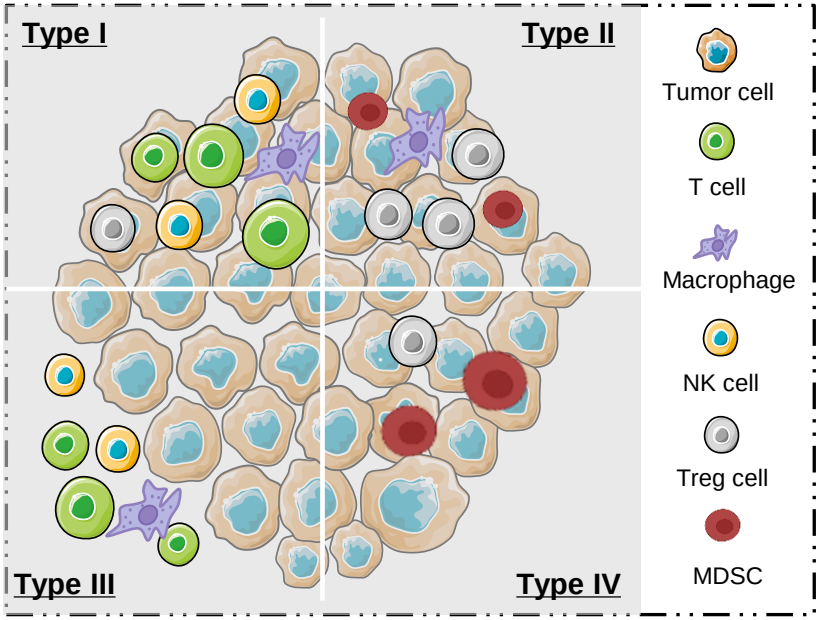
Type	MOA	Representative Products
Innate immune targets	• Innate immune effectors including NK cells, polymorphonuclear, macrophages, and monocytes can engage in direct tumoricidal activity or exert Fc-mediated effector functions against antibody-opsonized tumor cells utilizing multiple mechanisms. • The related signaling pathways include CD47-SIRPα, KIR-HIA, CD94-NKG2A and etc.	• **Magrolimab (Phase III)**
Adaptive immune targets	• By initiating and promoting the adaptive immunity or suppressing the adaptive immune resistance, the adaptive immune system's tumoricidal activity can be improved. Inhibiting adaptive immune resistance is the mechanistic basis of responses to PD-1 or PD-L1 blocking antibodies, and may be of relevance for the development of other cancer immunotherapy strategies. • The other related signaling pathways include CD28-CD80/CD86, CTLA4-CD80/CD86, and etc.al.	• PD-1: Keytruda®, Opdivo®, Libtayo®, Tyvyt® • PD-L1: Tecentriq®, Bavencio®, Imfinzi® • CTLA-4: Yervoy®
Tumor microenvironment & Cytokines	• Cytokines have been used as cancer immunotherapy for decades, and they work by one of two general mechanisms: either by exerting a direct antitumor effect or by indirectly enhancing the antitumor immune response by adjusting the tumor microenvironment.	• IL-2: Ontak®, Proleukin® • IFN-α: Multiferon® , Pegasys®
Cellular Immunotherapy	• Cellular Immunotherapy involves infusion of ex vivo activated and expanded tumor-specific immune cells into the patient. • Cellular Immunotherapy mainly includes dendritic cell/cytokine-induced killer cells (DC-CIK) and adoptive cell therapy (ACT), etc.	• CAR-T: Kymriah®, Yescarta® • TCR-T

Source: Literature Review, Frost & Sullivan Analysis

Overview of Tumor Microenvironment

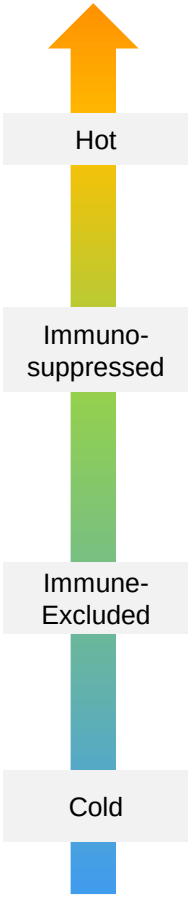
- According to lymphocyte infiltration, solid tumors are classified as hot (inflamed tumors), immunosuppressed, immune-excluded and cold (immune deserts). The degree of lymphocyte infiltration in the TME exert a critical impact on treatment response.

Overview of Tumor Microenvironment



- The tumor mass consists not only of a heterogeneous population of cancer cells but also a variety of cells, secreted factors and extracellular matrix proteins, collectively known as the tumor microenvironment (TME). Cellular composition of TME including various cell types, like endothelial cells, fibroblasts, immune cells, etc.

Classification of Tumor Microenvrionment



Type I
Highly infiltrated and inflamed

- Levels of immunosuppressive molecules lifted (ex. PD-L1)
- Mutational burden-MSI-H increased
- Levels of pro-inflammatory molecules lifted
- High Immunoscore

Type II
Some infiltration but not inflamed

- Immunosupressive environment
- Inhibition of immune cell recruitment and expansion or dysfunctional TILs activation (ex. T-cell exhasution)
- Low inflammation
- MDSC and Treg recruitment

Type III
T cells found only at the invasive margin

- Low T cell infiltration
- T cells found at the invasive margin
- Loss of T cell activation by APC

Type IV
Very low infiltration and not inflamed

- Very low or none infiltration
- Low mutational burden
- Poorly inflamed
- Low or none immunogenicity

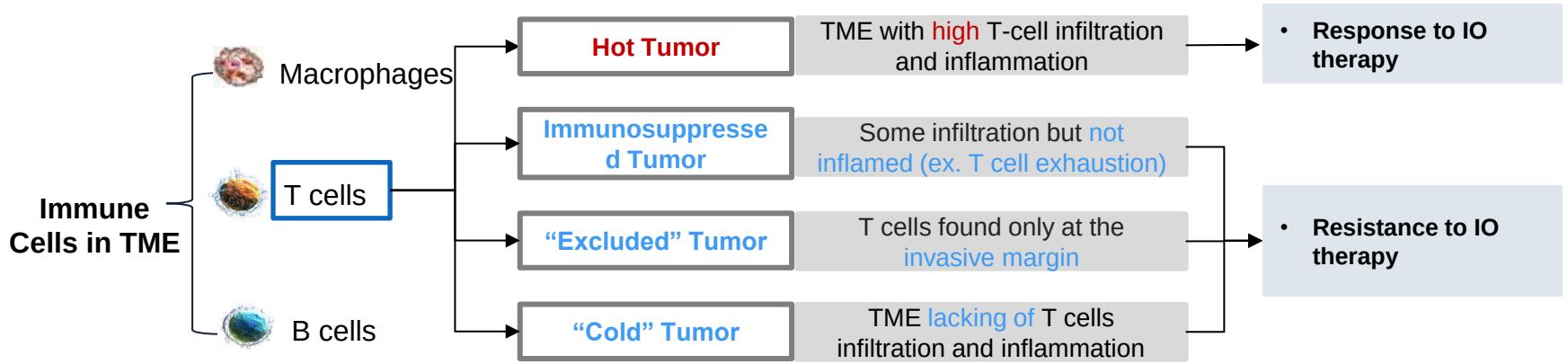
Source: Frost & Sullivan Analysis

Limitation of T cell-based Therapy

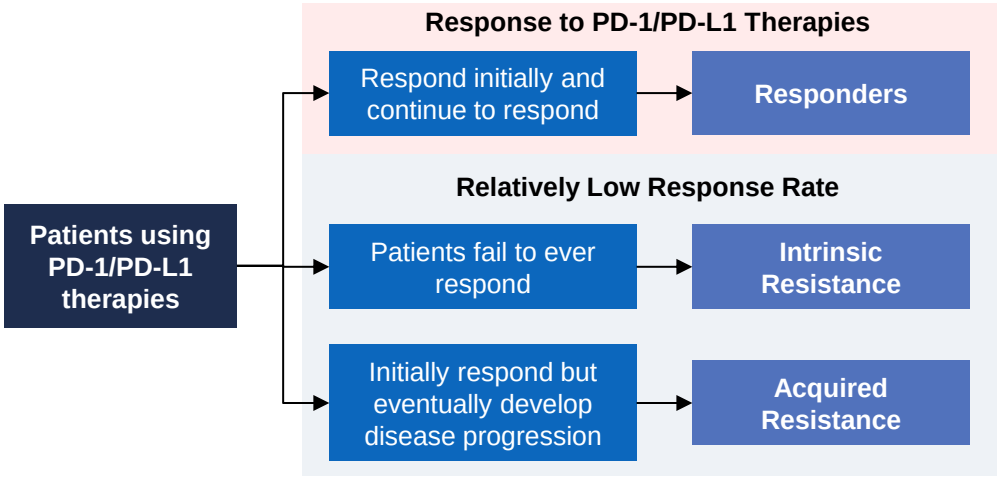
Case Study1: Limitation of PD-1/PD-L1 mAb

- Antitumor responses mediated by Immune checkpoint inhibitors (ICIs) rely on the activation and infiltration of T cells capable of recognizing and killing tumor cells. A lack of T cells in tumors or dysfunction of T cells can lead to resistance to IO therapy of this type.

Effects of TME on IO Therapy



Response and Resistance to PD-1/PD-L1 Therapies



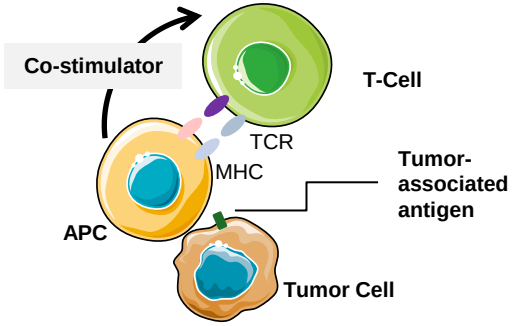
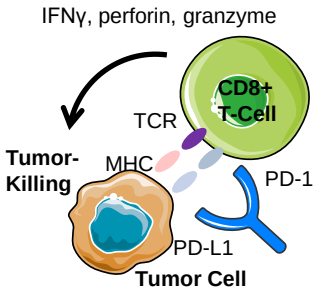
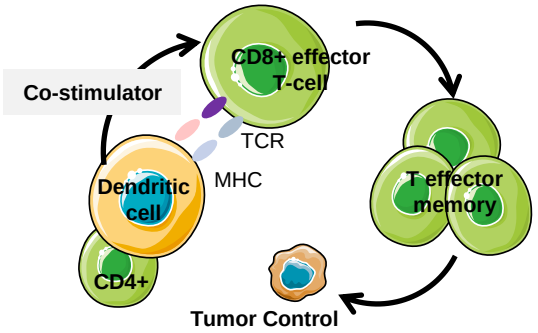
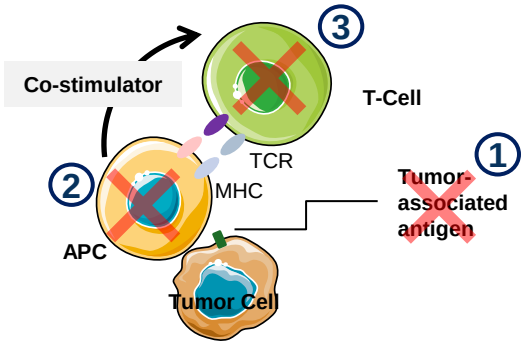
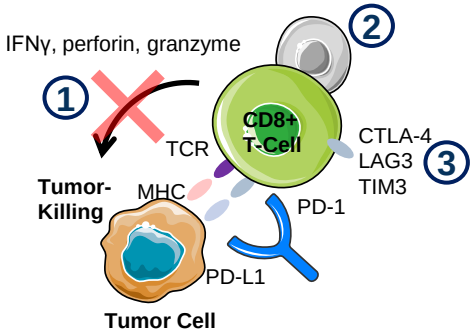
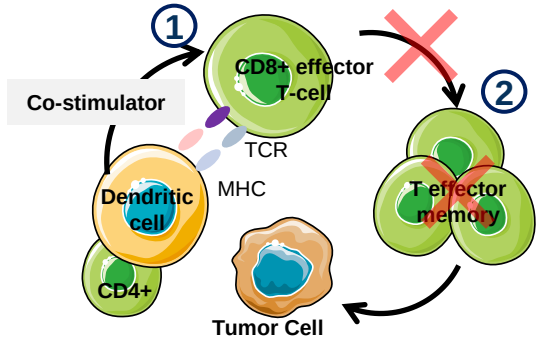
- PD-1/PD-L1 monoclonal antibodies have changed the treatment landscape of many tumors, whereas **response rate remains relatively low in many tumors,** which indicates either **intrinsic resistance or acquired resistance** to PD-1/PD-L1 therapies.
- A major factor is **the paucity of tumor T cell infiltration or dysfunctional/uninflamed T cell**, which limits the ability of T cells to kill tumors.

Source: Frost & Sullivan Analysis

Limitation of T cell-based Therapy

Case Study1: Limitation of PD-1/PD-L1 mAb

Resistance to PD-1/PD-L1 Therapies

	Formation of tumor reactive T-cells	Activation of effector T-cell function	Formation of effector memory T-cells
Response			
Intrinsic/Acquired Resistance	 1. Lack of sufficient or suitable neo-antigens. 2. Impaired processing or presentation of tumor antigens 3. Impaired intra-tumoral immune infiltration	 1. Impaired IFNγ signaling 2. Immune suppressive cells 3. Alternate immune checkpoints	 1. Severe T-cell exhaustion 2. T-cell epigenetic changes
	• Leading to intrinsic resistance and acquired resistance to PD-1/PD-L1 therapies.	• Leading to intrinsic resistance and acquired resistance to PD-1/PD-L1 therapies.	• If formation of T effector memory cells is impaired then clinical response could fade leading to **acquired resistance or recurrence of disease** following discontinuation of therapy.

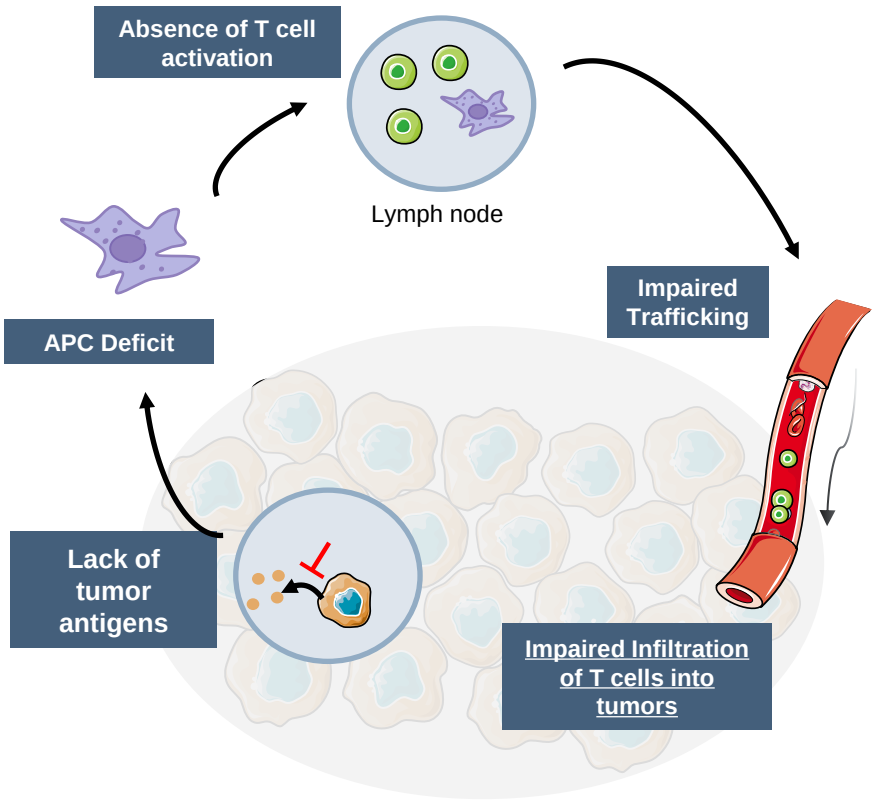
Source: Frost & Sullivan Analysis

Overview of Tumor Microenvironment

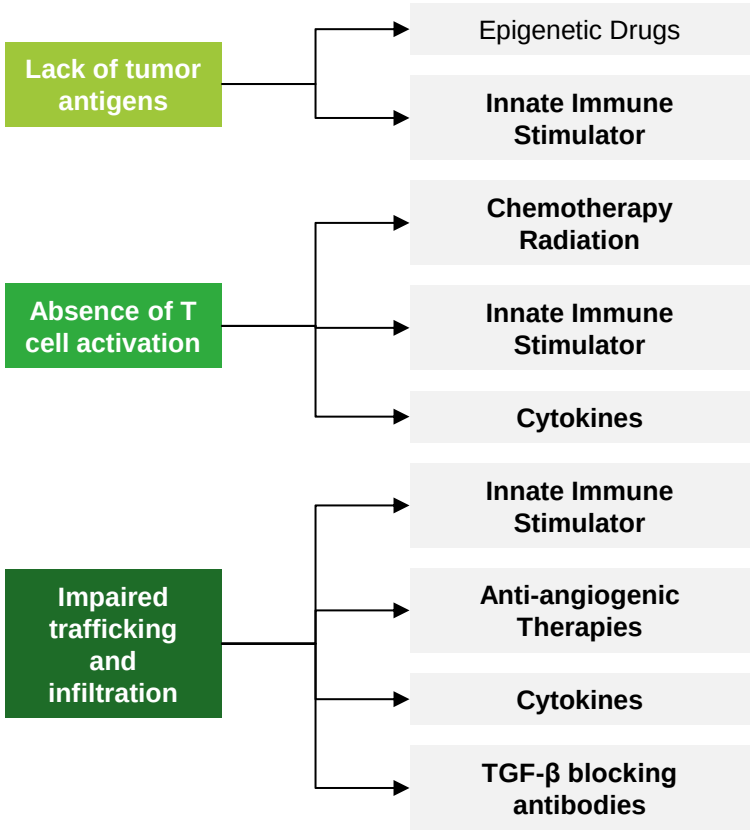
TME of Immunosuppressed, Excluded and Cold tumor

- The TME of immunosuppressed, excluded and cold tumor is characterized by lack of tumor antigens, APC deficit, absence of T cell activation or impaired trafficking and infiltration of T cells.
- In order to achieve satisfactory therapeutic effects of T-cell based therapy, regulation of immunosuppressive TME is required, which could be achieved through innate immune stimulator, cytokines, anti-angiogenic therapies and etc.

Immunosuppressive TME



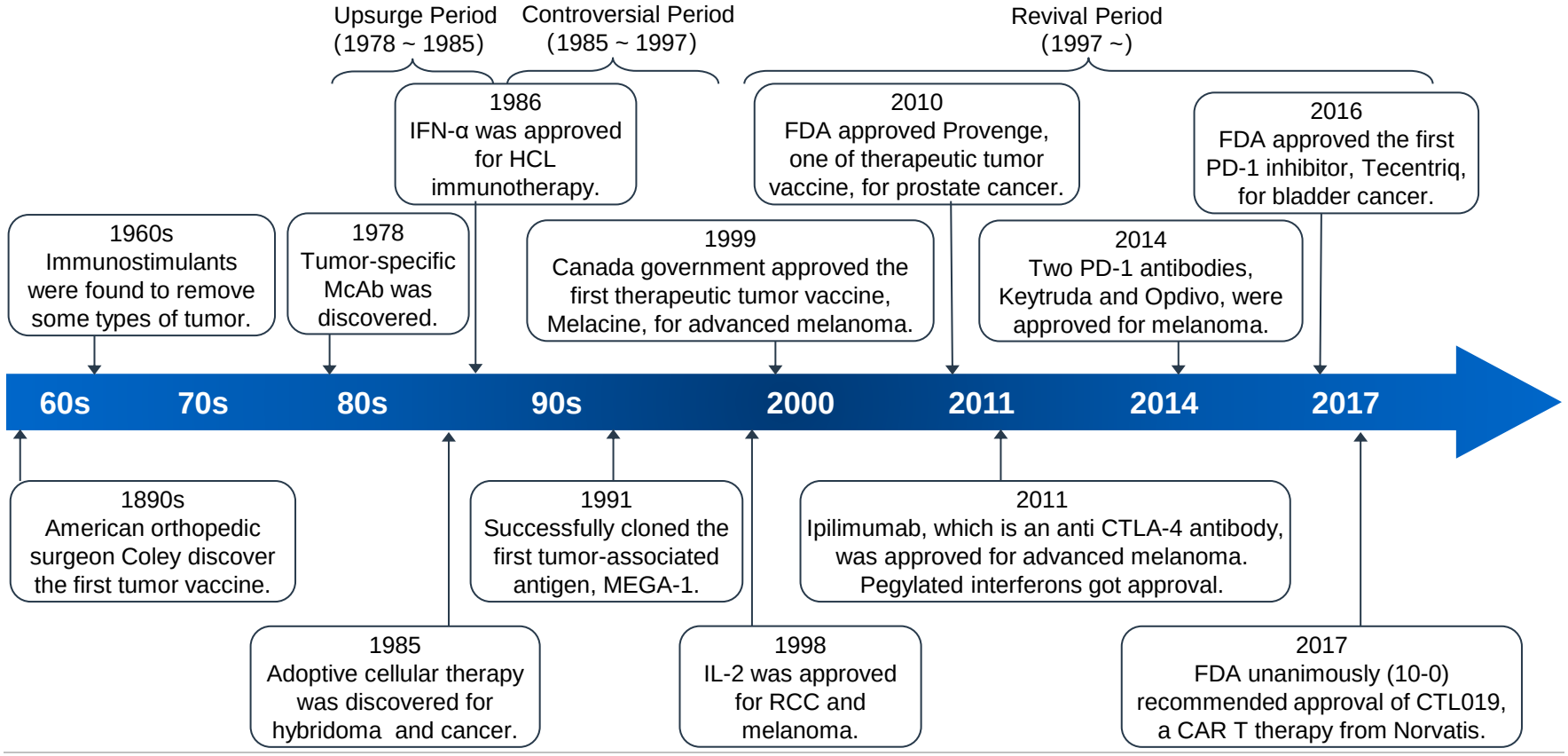
Therapeutic Approaches



Source: Frost & Sullivan Analysis

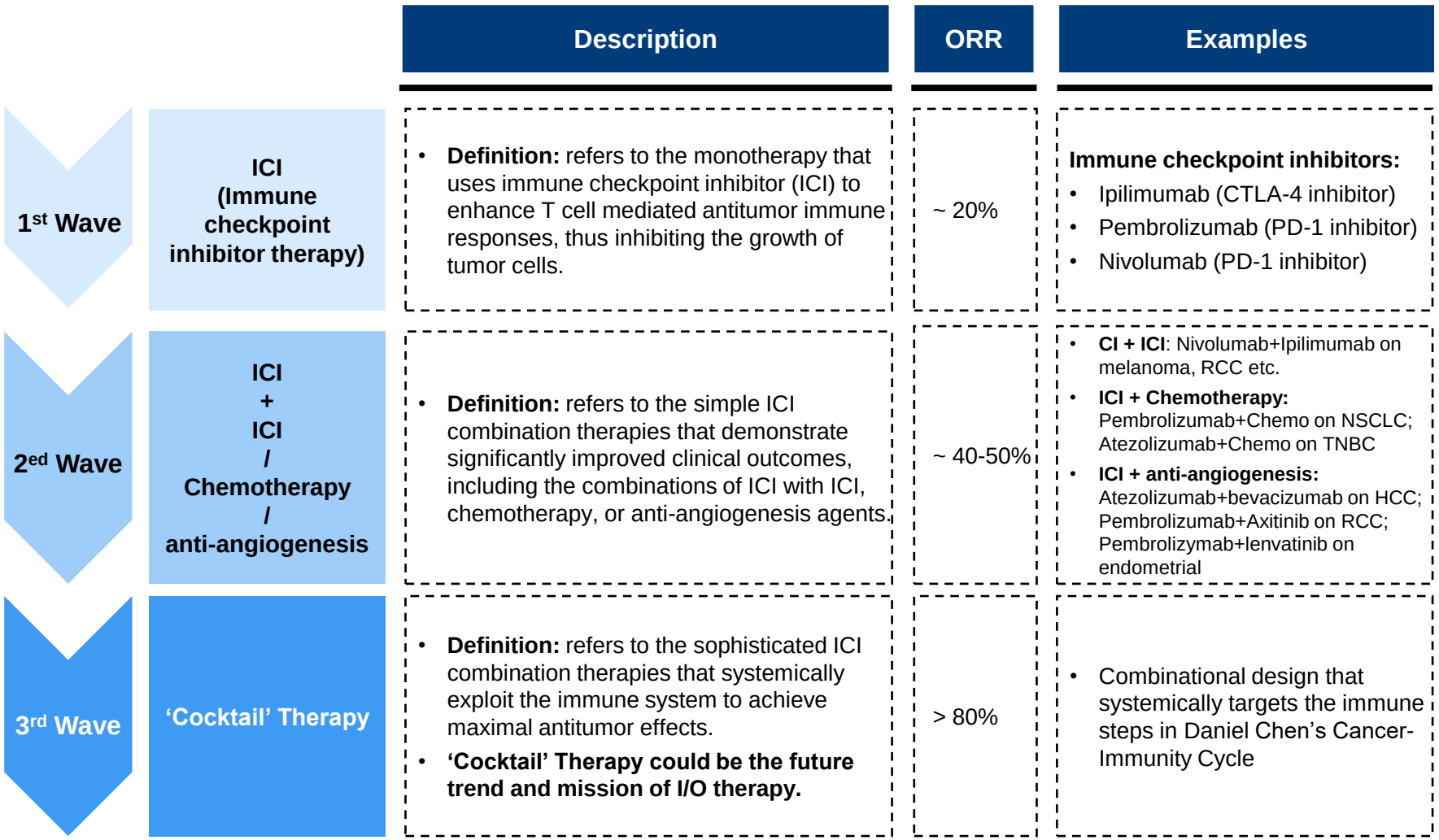
Overview of Development Path of Immuno-Oncology Therapy

- Reviewing the development of cancer treatment, the immunotherapy has been emerging since 1890s and experienced three phases on the way.
- The development of cancer immunotherapy has speeded up since 2010, when FDA approved the first vaccine for prostate cancer. The immunotherapy is one of the hottest sectors in healthcare industry with a strong growth momentum.



Source: Frost & Sullivan Analysis

Development Path of Immuno-Oncology Therapies



Source: Literature Review, Frost & Sullivan Analysis

Clinical Applications of Immuno-Oncology Therapies

Immuno-Oncology Therapies in China

- Compared with traditional treatment methods, cellular immuno-oncology therapy is expected to become the mainstream treatment for tumors in the future because it can be clinically tailored to specific patients/diseases, enhance their body immune function, and is safer and more durable. At present, most of domestic clinical anti-tumor therapy still makes use of T cells, but clinical trials related to cellular immunotherapy are also being accelerated.
- In order to overcome the problem of drug resistance in immuno-oncology therapy and avoid patients' non-response to treatment, clinical measures should be taken to overcome drug resistance at different stages of immune response according to the characteristics of different immunophenotypes, as well as considering different links or targets of action and different combinations of drugs.

Clinical Applications

1 PD-1/PD-L1

- PD-1/PD-L1 inhibitors are mainly used to eliminate tumors by inhibiting the immune escape of tumor cells and enhancing the immune response of T cells. Although PD-1/PD-L1 inhibitors inhibitors have achieved good efficacy in a variety of malignancies, including melanoma, non-small cell lung cancer and renal cell carcinoma.

2 CAR-T

- CAR-T therapy refers to the genetic engineering to obtain T cells carrying specific receptors for tumor antigens and transfuse them back to patients, so as to enhance the tumor-killing effect of T cells by recognizing tumor-related antigens, accurately locating tumor targets and expressing them for a long time. This therapy is effective in the treatment of hematological tumors such as leukemia, lymphoma, multiple myeloma or cancers such as liver and ovarian cancers.

3 Combination immuno-oncology strategy

- Combination therapy strategies can improve or activate antitumor immune responses and overcome resistance mediated by different mechanisms. Immunotherapy is most often used in combination with conventional radiotherapy. Chemotherapeutic agents can directly or indirectly stimulate the immune response and increase tumor immunogenicity, thereby improving progression-free survival and overall survival and extending the clinical benefit of immune-combination chemotherapy.
- Bispecific antibody therapy can simultaneously bind two different epitopes or antigens to achieve a synergistic multi-pathway resistance function. For example, the bifunctional fusion protein M7824 (MSB0011359C) antagonizes both PD-L1 and "captures" transforming growth factor β to more effectively inhibit tumor growth and metastasis, and reduces the complexity of clinical development and drug side effects.

Source: WHO, Frost & Sullivan Analysis

Benefits and Drawbacks of Immuno-Oncology Products

Type	Overview	Benefits	Drawbacks
Cellular Immunotherapy	• Adoptive cell transfer, which is a treatment that attempts to boost the natural ability of your T cells to fight cancer. In this treatment, T cells are taken from your tumor.	• CAR T treatment showed encouraging results in clinical trials. • Cancer could not be found after treatment for many patients.	• Cytokine release syndrome. • Long-term side effects are still unclear for CAR T treatment. • Limited efficacy in solid tumor
Cytokines	• Cytokines are proteins that modulate the expansion, activation, and survival of lymphocytes. They are thought to facilitate T cell, B cell, and NK cell proliferation and effector function, thereby strengthening the antitumor response.	• Cytokines can inhibit the growth of tumor cells, and significantly prolong the life of patients.	• Lack specificity ,and toxicity can result in autoimmunity or tissue damage.
Therapeutic Cancer Vaccine	• Therapeutic cancer vaccines are designed to stimulate the patient's own immune system against tumor antigens. By triggering the immune system, therapeutic vaccines can initiate a durable anti-tumor response that can attack tumor cells and lead to improved survival.	• Side effects are mild, while a few patient might have severe symptoms, like problem breathing and high blood pressure.	• Therapeutics effects are limited.
Checkpoint Monoclonal Antibodies	• Checkpoint inhibitors, which are drugs that help the immune system respond more strongly to a tumor. These drugs work by releasing "brakes" that keep T cells (a type of white blood cell and part of the immune system) from killing cancer cells. These drugs do not target the tumor directly. Instead, they interfere with the ability of cancer cells to avoid immune system attack.	• Checkpoint mAbs can block the pathway and simulate the immune system.	• Allergic reaction and side effects. • Antibodies can not stimulate T cells attack tumors.
Oncolytic Virus	• Oncolytic viruses can replicate in cancer cells but not in normal cells, leading to lysis of the tumor mass and can stimulate the immune system by enhancing antigen release/recognition and subsequent immune activation to counteract the immune evasiveness of malignant cells as well.	• Genetically modified oncolytic viruses can specifically recognize tumors, which increases potency and reduces side effects	• The efficacy may be diminished by the presence of circulating antibodies.

Source: BIOPHARM INTERNATIONAL, 2022, 35(1): 32-37., Signal Transduction and Targeted Therapy, 2022, 7(1): 1-28, Monoclonal antibodies. BoD–Books on Demand, 2021., Front Immunol. 2021 May 5;12:626616., Seminars in cancer biology. Academic Press, 2020, 64: 1-12, Int J Mol Sci. 2020 Jul 31, Cell Mol Immunol. 2020 May;17(5):451-461., BioDrugs, 2014, 28(4): 331-343., Br J Pharmacol.2009 May;157(2):220-33., Frost & Sullivan Analysis

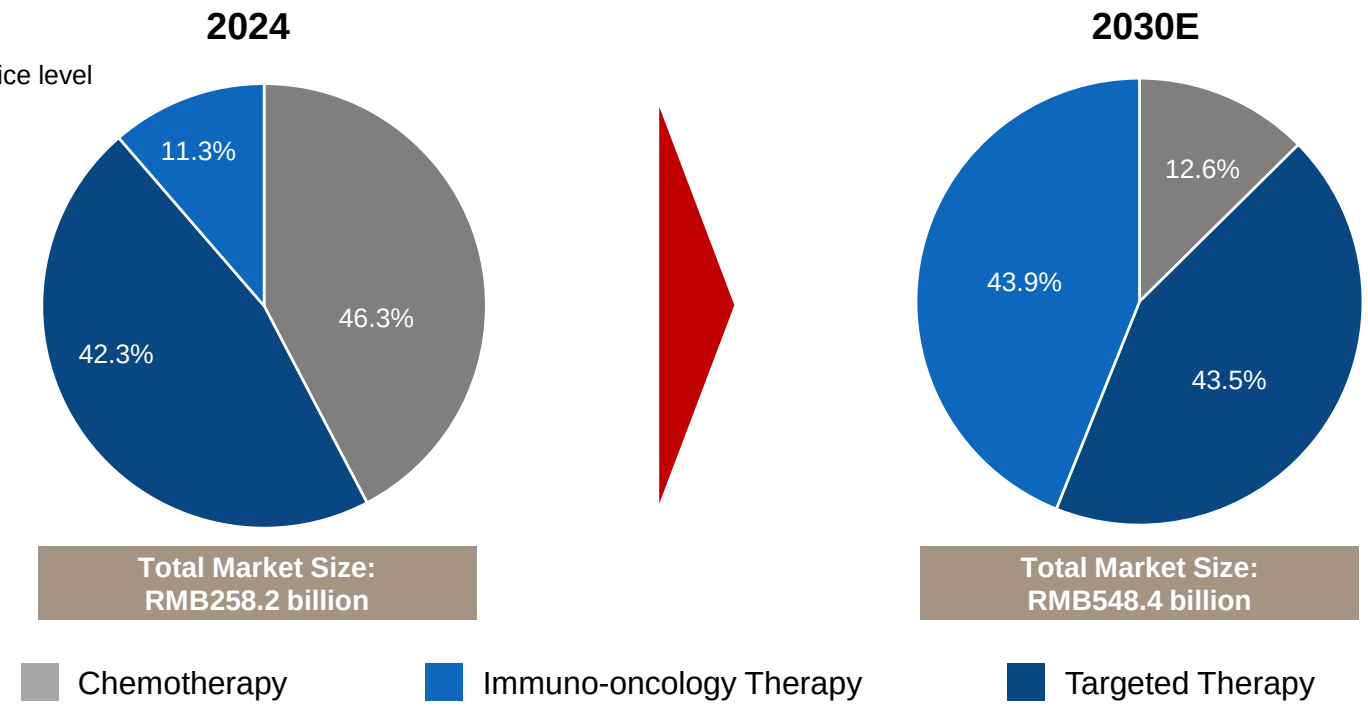
Breakdown of China Oncology Market by Therapy, 2023 and 2030E

- Currently, China oncology market is dominant by chemotherapy drugs which takes up to 46.3% of total. Targeted drugs including small-molecularly targeted drugs and biologics, which take a proportion of 42.3%, leaving 11.3% for immuno-oncology therapy in 2023.
- With reimbursement policies, new drug development and patients' increasing affordability, the targeted therapy and immuno-oncology therapy would occupy most of the market by 2030. It is expected that the share of immuno-oncology therapy approaches 43.9% while targeted drugs share would reach 43.5%.

Breakdown of China Oncology Market by Therapy, 2024 and 2030E

Billion RMB

At wholesale price level



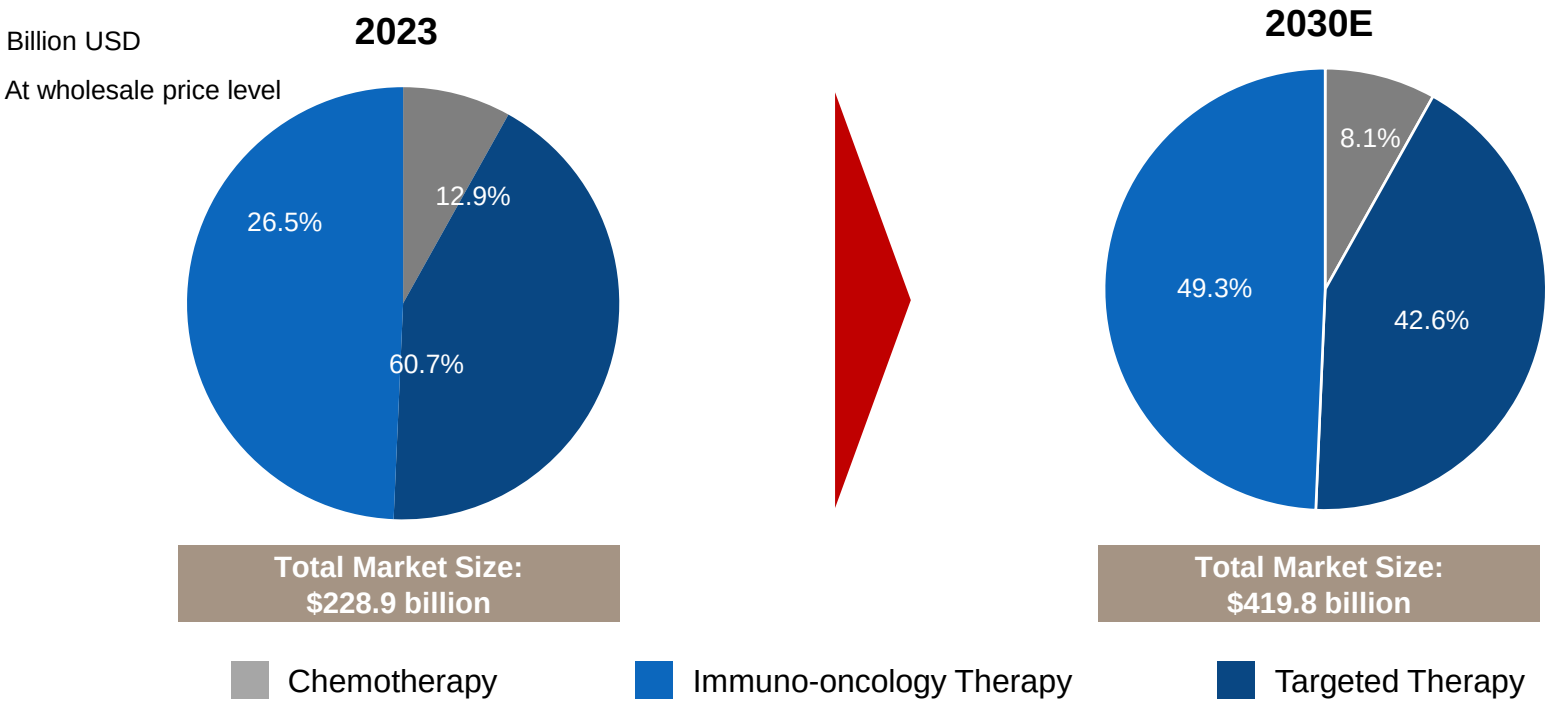
Chemotherapy includes chemical drugs, traditional Chinese medicine injections and adjuvant anti-tumor drugs.

Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, NCCR, Frost & Sullivan Analysis

Breakdown of Global Oncology Market by Therapy, 2023 and 2030E

- Currently, global oncology market is dominant by targeted therapy, which takes up to 60.7% of total market share. Chemotherapy is taking a proportion of 12.9%, the remaining 26.5% corresponds to immuno-oncology therapy in 2023.
- It is expected that the share of immuno-oncology therapy approaches 47.9% while targeted drugs share would reach 43.9%.

Breakdown of the Oncology Market by Therapy in Global, 2023 and 2030E



Chemotherapy includes chemical drugs and adjuvant anti-tumor drugs.

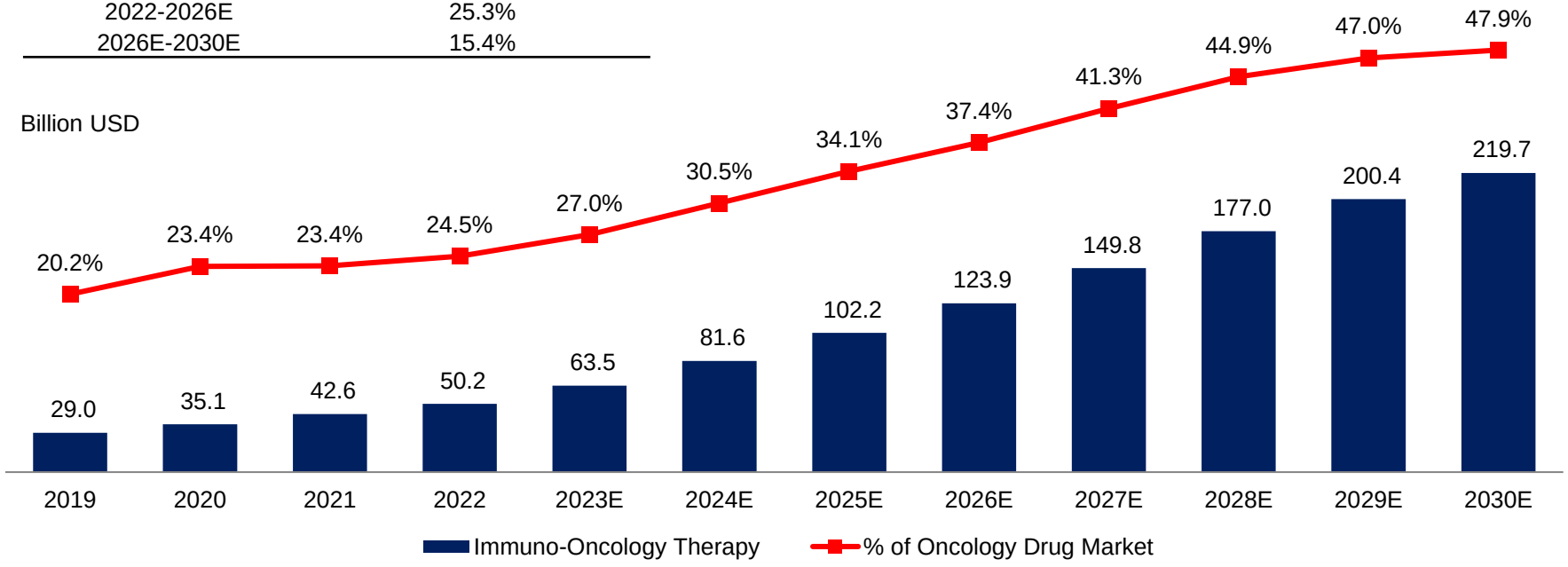
Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, FDA, IARC, GLOBOCAN, Frost & Sullivan Analysis

Global Immuno-Oncology Therapy Market, 2019-2030E

- Immuno-Oncology therapies are emerging cancer therapies in global market, including the therapies of cytokines, therapeutic cancer vaccine, checkpoint monoclonal antibodies and adoptive cell transfer therapies. In 2022, the total Immuno-Oncology therapy market reached USD50.2 billion, growing from USD 29.0 billion in 2019. In future, with the sales growth of checkpoint monoclonal antibodies market and continuously approval of new therapies like CART, the market will climb to USD123.9 billion in 2026, and USD219.7 billion in 2030, with a CAGR of 25.3% from 2022 to 2026 and 15.4% from 2026 to 2030 respectively

Global Immuno-Oncology Therapy Market, 2019-2030E

Period	CAGR
2019-2022	20.1%
2022-2026E	25.3%
2026E-2030E	15.4%



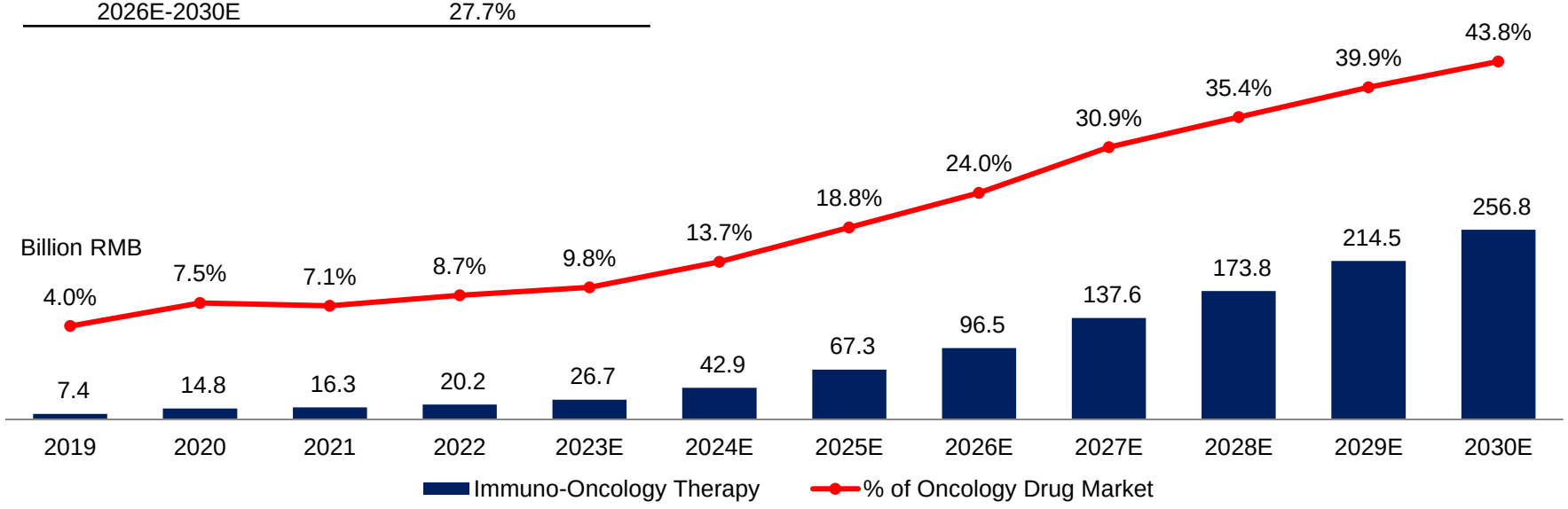
Source: Frost & Sullivan Analysis

China Immuno-Oncology Therapy Market, 2019-2030E

- China Immuno-Oncology therapy market has increased dramatically in the past few years from RMB7.4 billion in 2019 to RMB20.2 billion in 2022, representing a CAGR of 40.1% from 2019 to 2022. Also, it is expected to increase to RMB 96.5 billion and RMB256.8 billion in 2026 and 2030 respectively, with the CAGR of 47.8% from 2022 to 2026, and 27.7% from 2026 to 2030.
- As for the percentage of Immuno-Oncology therapy market to oncology drug market, it also indicates a strong growth trend. In 2019, the Immuno-Oncology therapy market only occupied 4.0% of oncology drug market, which increased to 8.7% in 2022.

China Immuno-Oncology Therapy Market, 2019-2030E

Period	CAGR
2019-2022	40.1%
2022-2026E	47.8%
2026E-2030E	27.7%



Source: Frost & Sullivan Analysis

Growth Drivers of Immuno-Oncology Therapy Market

Growing Patient Pool	• The increasing new cases of cancer patients, especially the treatment naïve patients, will drive the cellular immunotherapy development in China. New cases of cancer patients are increasing stably in the past, reaching 4929.0 thousand in 2023 in total. However, the enlarging patient pool is still facing limited cancer treatment options. IO therapy, which is able to address unmet clinical needs with durable efficacy and less side effects, represent significant market opportunity in China market.
Use of Combined Targets	• Therapies combined two or more targets, is increasingly being attempted in cancer therapy. The therapies use combined targets enhances efficacy because it targets key pathways in a characteristically synergistic or an additive manner. • For example, it has revealed by ongoing trials that PD-1/PD-L1 in combination with cytokines may lead to enhanced T cell infiltration due to the microenvironment modulation. With the investigation on more potent combination such as PD-1/PD-L1 inhibitor with CD47 targeted drugs, it will enrich the varieties of treatment combinations and expand the IO therapy market.
Emerging targets of Immuno-Oncology	• Since the approval of CTLA-4 inhibitor (ipilimumab) in 2011, and especially the approval of over 10 PD-1/PD-L1 inhibitors worldwide, the IO therapy market has maintained a high rate of booming growth, with a CAGR of 24.3% and 80.3% respectively globally and in China from 2018 to 2022. • Such a rapid market growth was a result of previous R&D effort made on target discovery, which has been placed great emphasis currently, with new IO targets such as SIRPa, OX40, TIGIT, etc kept emerging, forming a evern larger reservoir of promising targeted drug candidates that will likely to be commercialized in the future. In this way, the IO therapy market is expected to expand further.
Advancement of Treatment Line	• On June 15, 2018, Opdivo (Nivolumab) was approved as a second-line drug for the treatment of advanced non-small cell lung cancer (NSCLC) with negative driver gene mutation, becoming the first PD-1 mAb approved in China. On September 30, 2019, Keytruda (pembrolizumab) became the first single drug approved for first-line treatment of all locally advanced or metastatic NSCLC with positive PD-L1 expression and no EGFR or ALK mutation. Both drugs are PD-1 inhibitors, this means that tumor immunotherapy is approved from second-line to first-line treatment in just 15 months due to good clinical trial results. For the tendency to shift from second or later line toward first-line treatment, it has a great chance to benefit more patients, which will drive IO therapy market accordingly.

Source: Frost & Sullivan Analysis

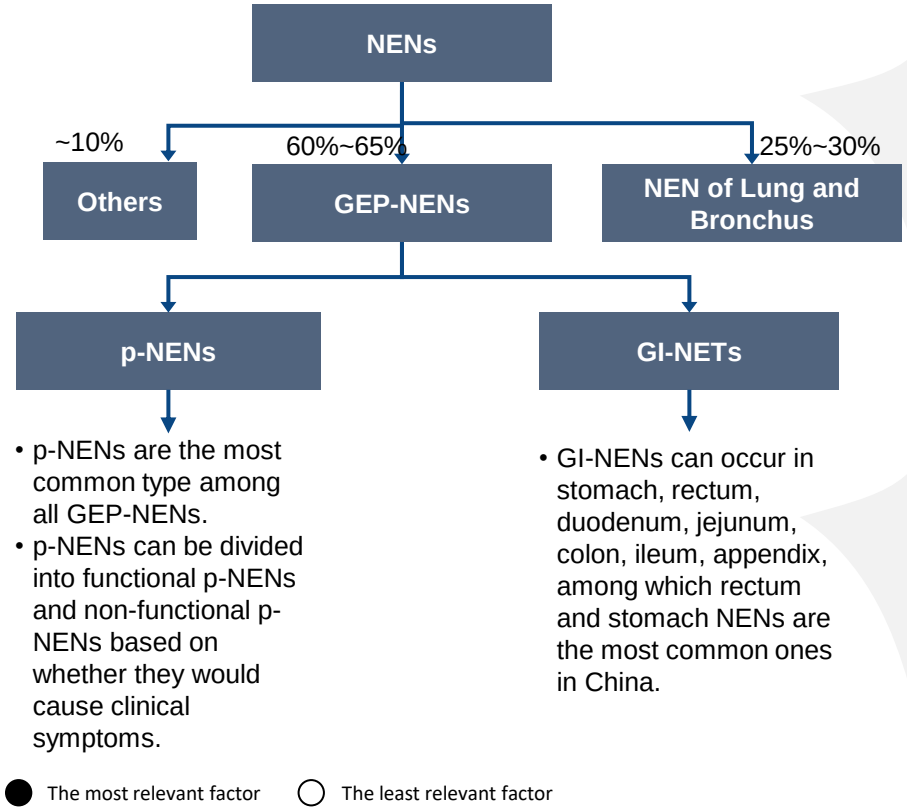
Future Trends of Immuno-Oncology Therapy Market

Wider Indication Coverage	• Even though the efficacy of some types of IO therapies haven't been fully approved in all tumors types yet, the high variety of solid tumor types and their escalating incidences around the globe have reflected the huge market potential. Additionally, CD47 targeted drugs are not only validated among hematological tumors such as MDS, AML, the efficacy of which is also demonstrated in some solid tumors. For example, ALX148 has demonstrated superior efficacy in both HNSCC and HER2+ Gastric/GEJ cancers. Driven by the goal to achieve better treatment outcomes, it is expected that in the future, IO therapies such as CD47 targeted IO therapies and some cellular immunotherapies will be designed make them applicable at a wider range.
Enhanced Efficacy through Different Synergic Strategies	• Currently, the majority of IO therapies are single targets, though efficacious compared with traditional chemotherapies, still have various limitations. For example, PD-1/PD-L1 non-responders can take up to over 80% of all patients for a certain cancer type, which arose the need for new treatment strategies, especially the ones that could effectively leveraging previously well studies targets and createe synergic effect based upon them. In specific, both combination therapy bifunctional proteins such as immunocytokines and bispecific antibodies are synergic strategies of these type, with clinical evidence showing that efficacy is enhanced through mechanisms such as better recruit the effector cells to cancerous site or enhance the directional killing. It is expected that these synergic treatment strategies will be more diverse in the future, leading to an enhanced efficacy.
High Requirement on Adverse Event Management	• The rapid development of IO therapy has revealed some safety concerns that potentially cause harm to the body of the patients. For example, red blood cell related toxicity constitutes the major concern in CD47 targeted drugs while cytokine release syndrome (CRS) is one of the most common side effects in CAR-T cell therapy. Especially for CD47 targeted therapies, both Arch Oncology and Celgene discontinued their trials regarding CD47 trials due to safety concerns. • Despite the therapeutic benefit, it has risen an urgent need to minimize such risks of IO treated patients, which requires the IO therapy developers to be equipped with robust scientific understanding and thereby good development strategies so that the adverse event can be kept manageable and minimal.
Efficient R&D Platform	• The IO therapy market is currently experiencing fierce competition due to the realization of the great market potential. For example, though the first PD-1/PD-L1 inhibitor was approved only 7 years ago, there are currently over 10 PD-1/PD-L1 inhibitors approved worldwide, with more than 100 clinical trials ongoing. Similarly, only after 5 years since the first CAR-T cell therapy approval, more than 5 CAR-T cell therapies were approved. • Given such intensive market competition, it is apparent that manufacturers should develop and possess advanced R&D skills and technology to maintain competitiveness among players by pushing forward R&D progress efficiently. Thus, it is expected that in the future, having an efficient R&D platform is necessary for market players to capture market opportunity in IO therapy market.

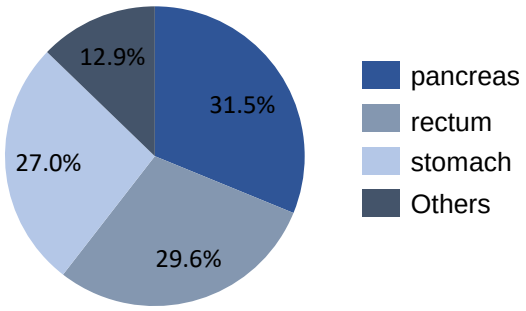
Source: Frost & Sullivan Analysis

Overview of Extra-pulmonary Neuroendocrine Carcinoma

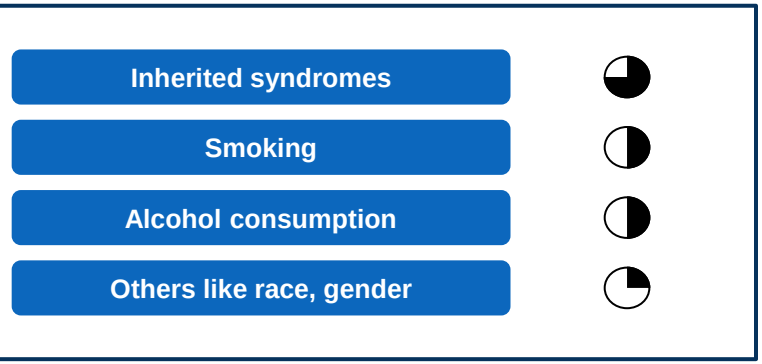
- Neuroendocrine neoplasm (NEN) originate from neuroendocrine cells, having neuroendocrine differentiation, expressing neuroendocrine markers and occurring in any organs all over the body, mainly including lung, stomach, pancreas, colon and rectum. Extra-pulmonary NENs roughly accounts for 65%-70% of total NENs. Extra-pulmonary NENs can be further divided into pancreatic NENs (p-NENs) and Gastrointestinal NENs (GI-NENs).
- Pathologically, according to the degree of differentiation, NEN can be divided into well-differentiated neuroendocrine tumors (NET) and poorly differentiated neuroendocrine carcinoma (NEC). NEC is characterized by an aggressive clinical course with early metastasis and frequent recurrence, accounting for around 20% of all NENs.



Occurrence Site of EP-NEN (China)



Risk Factors



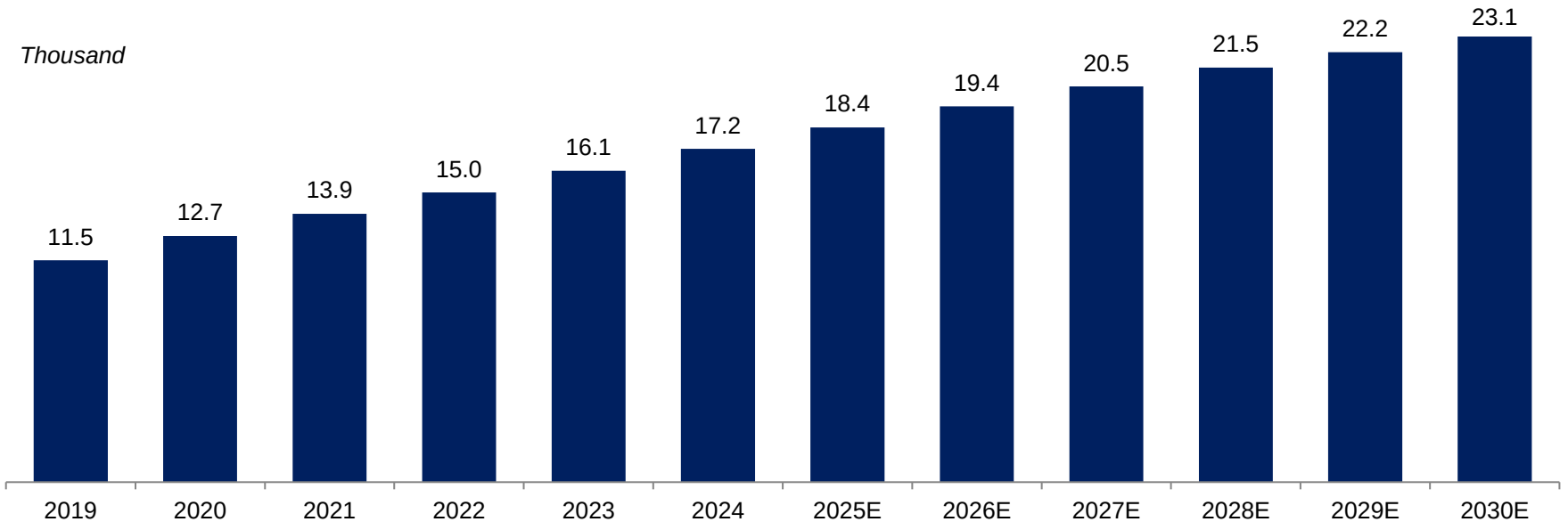
Source: Literature Review, Frost & Sullivan Analysis

Incidence of Extra-pulmonary Neuroendocrine Carcinoma in China, 2019-2030E

- In China, the number of new cases of extra-pulmonary neuroendocrine carcinoma rose to 17.2 thousand in 2024, showing a CAGR of 8.5% from 2019. This figure is expected to climb further to 20.5 and 23.1 thousand by 2027 and 2030, indicating a CAGR of 5.9% and 4.1% from 2024.

Incidence of Extra-pulmonary Neuroendocrine Carcinoma in China, 2019-2030E

Period	CAGR
2019-2024	8.5%
2024-2027E	5.9%
2027E-2030E	4.1%



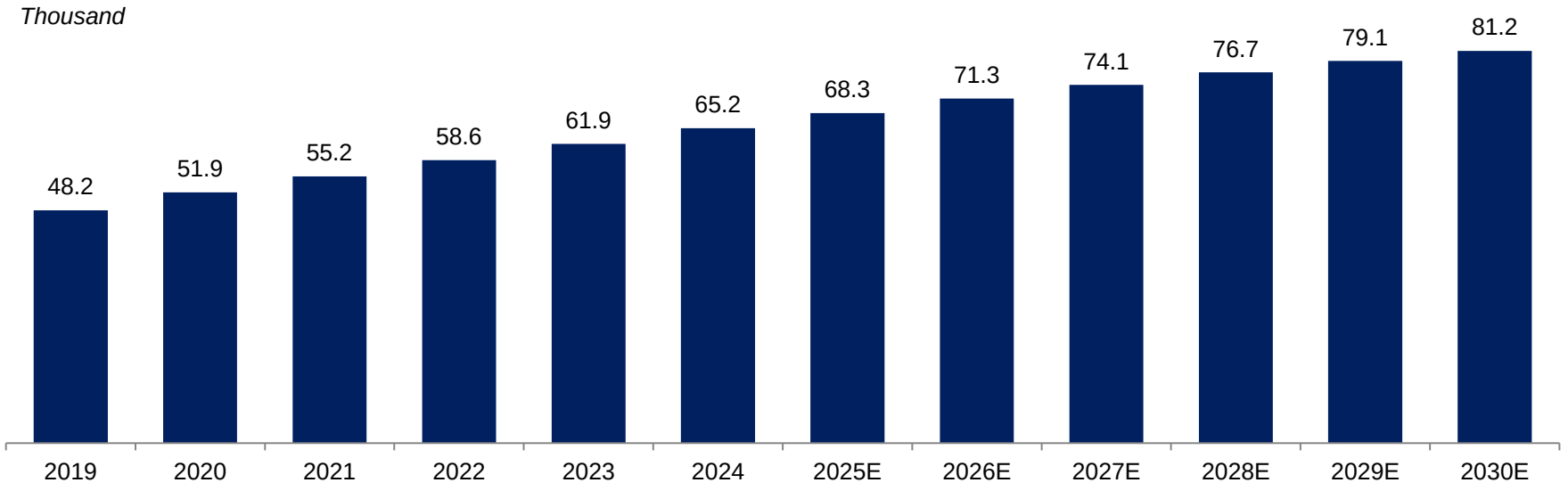
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Extra-pulmonary Neuroendocrine Carcinoma, 2019-2030E

- The global incidence of extra-pulmonary neuroendocrine carcinoma rose from 48.2 thousand to 65.2 thousand between 2019 and 2024, showing a CAGR of 6.2%. Projections suggest that this figure will further increase to 81.2 thousand by 2030, reflecting a CAGR of 3.7% from 2024 to 2030.

Global Incidence of Extra-pulmonary Neuroendocrine Carcinoma , 2019-2030E

Period	CAGR
2019-2024	6.2%
2024-2030E	3.7%



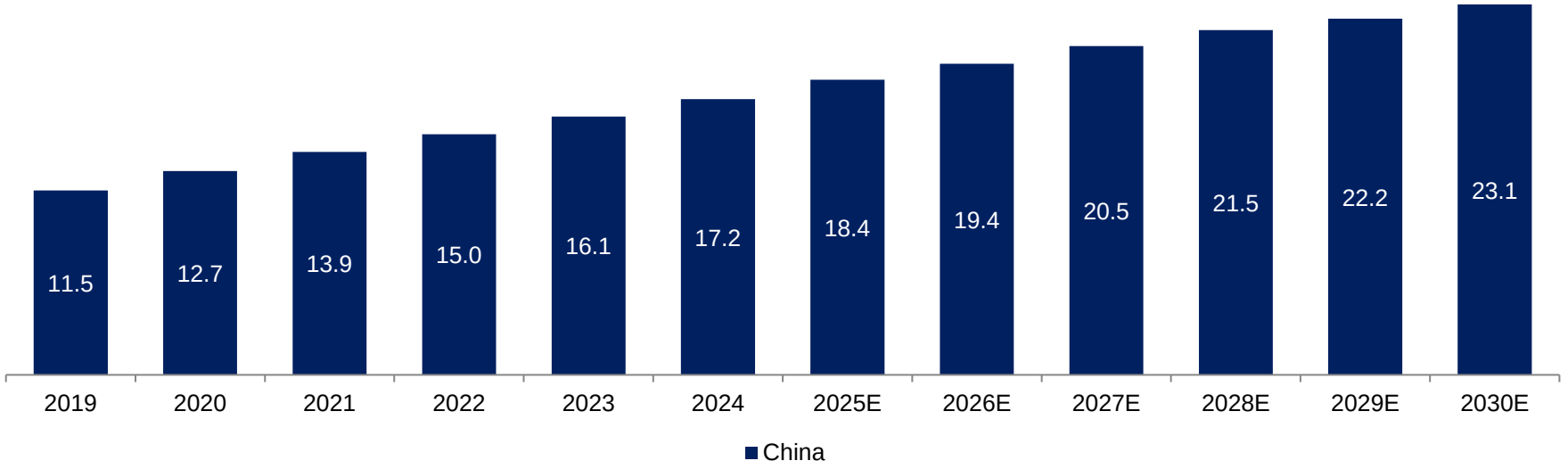
Source: IARC, Frost & Sullivan Analysis

Global Incidence of Extra-pulmonary Neuroendocrine Carcinoma by Region, 2019-2030E

Global Incidence of Extra-pulmonary Neuroendocrine Carcinoma by Region, 2019-2030E

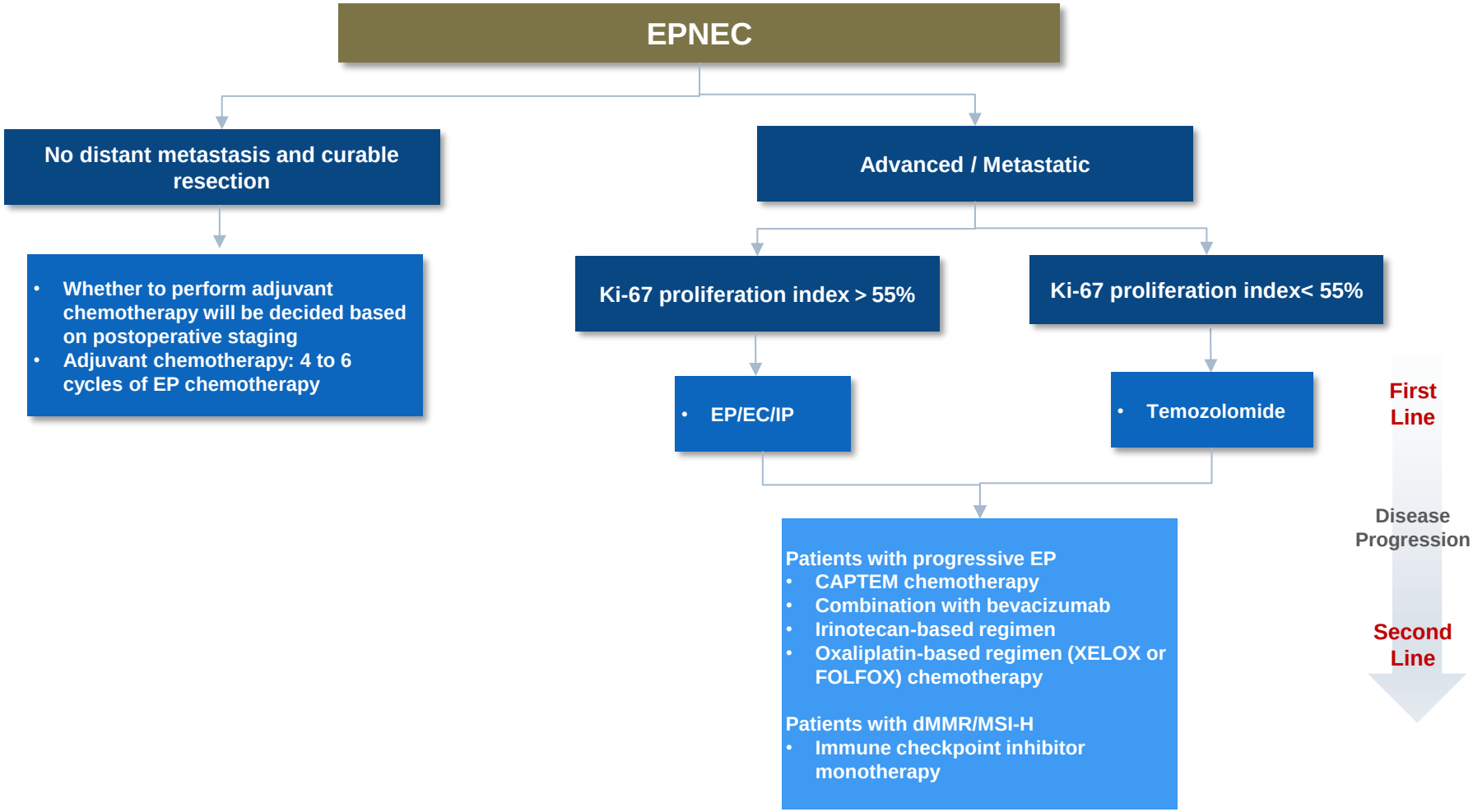
Period	CAGR			
	China	US	RoW	Total
2019-2024	8.4%	2.7%	6.2%	6.2%
2024-2030E	5.0%	2.3%	3.5%	3.7%

Thousand



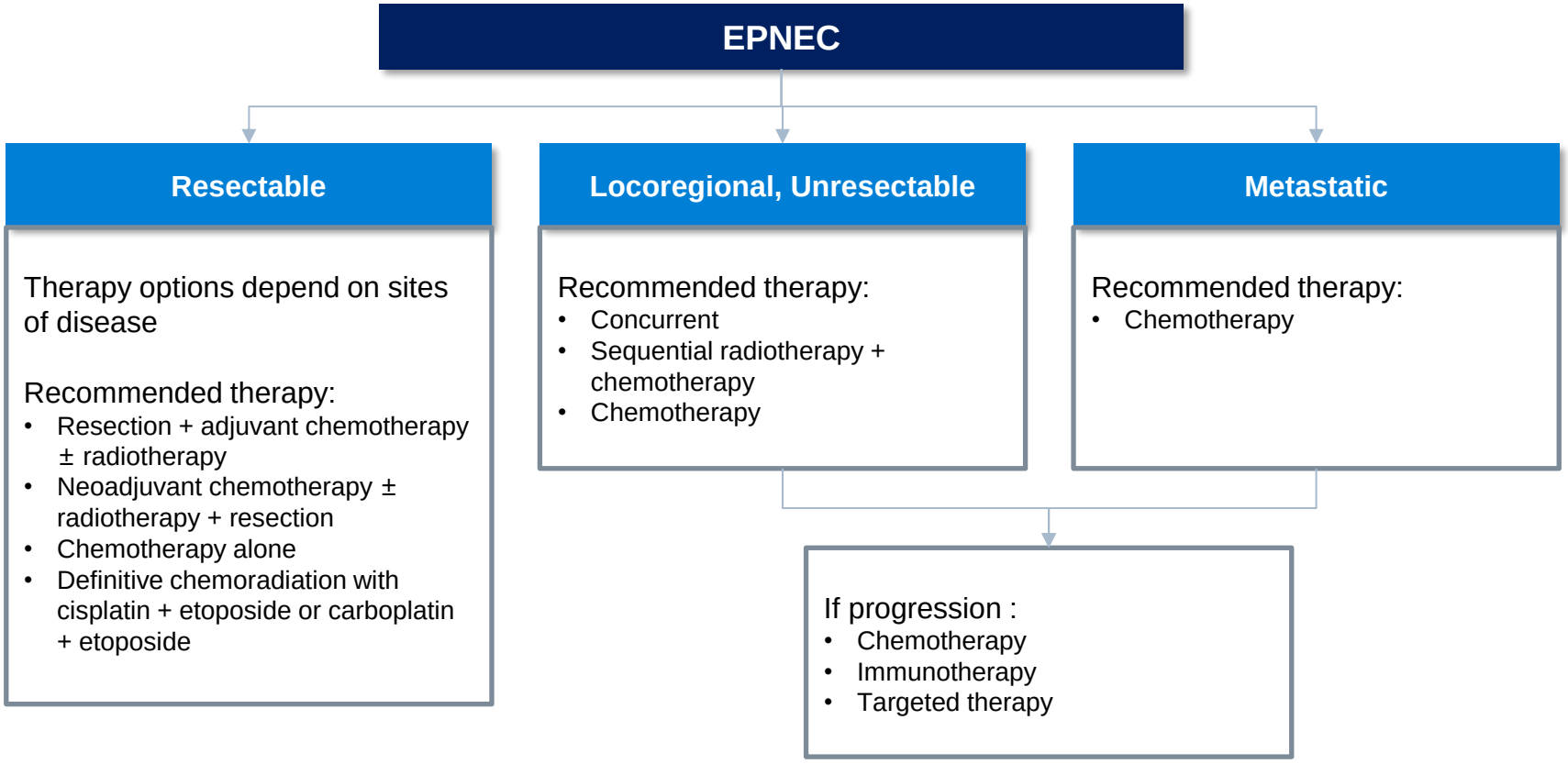
Source: IARC, Frost & Sullivan Analysis

Treatment Paradigm of EPNEC in China



Source: CSCO2023, Frost & Sullivan Analysis

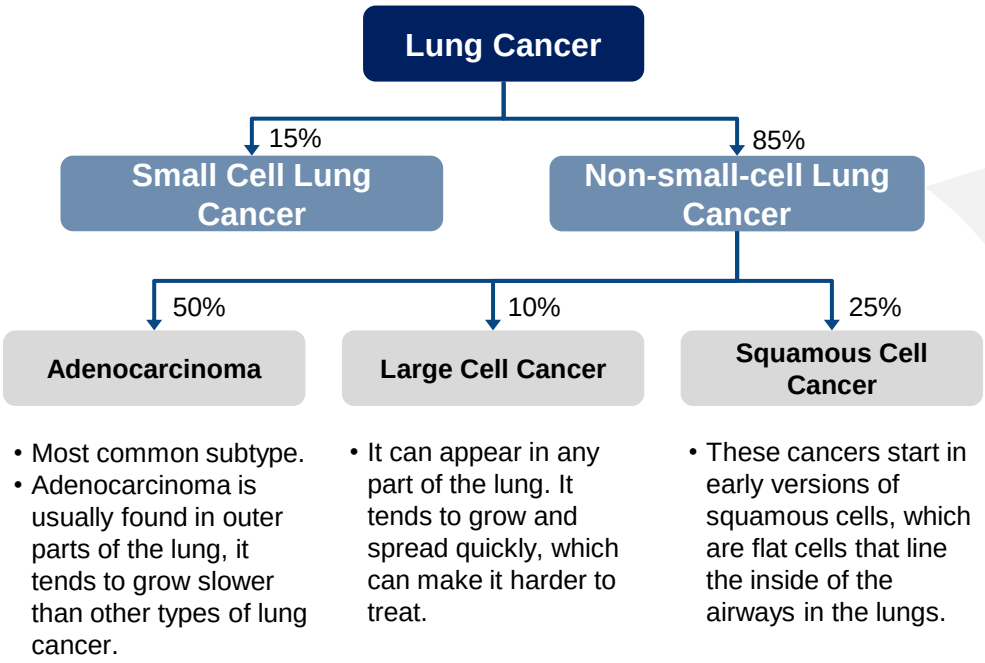
Treatment Paradigm of EPNEC in the US



Source: NCCN2024, Frost & Sullivan Analysis

Overview of SCLC

- Small cell lung cancer (SCLC) accounts for 15% of all lung cancer cases and is most commonly diagnosed in patients with histories of heavy smoking.
- In general, SCLC grows aggressively and is highly metastatic, resulting in a high mortality rate. As SCLC is often asymptomatic and progresses quickly, most patients are diagnosed at an advanced stage with distant metastases, known as the extensive stage.
- The high heterogeneity of SCLC makes developing targeted therapies difficult due to the lack of common, actionable oncogenic drivers.
- Most patients with lung cancer are diagnosed at an advanced or metastatic stage.



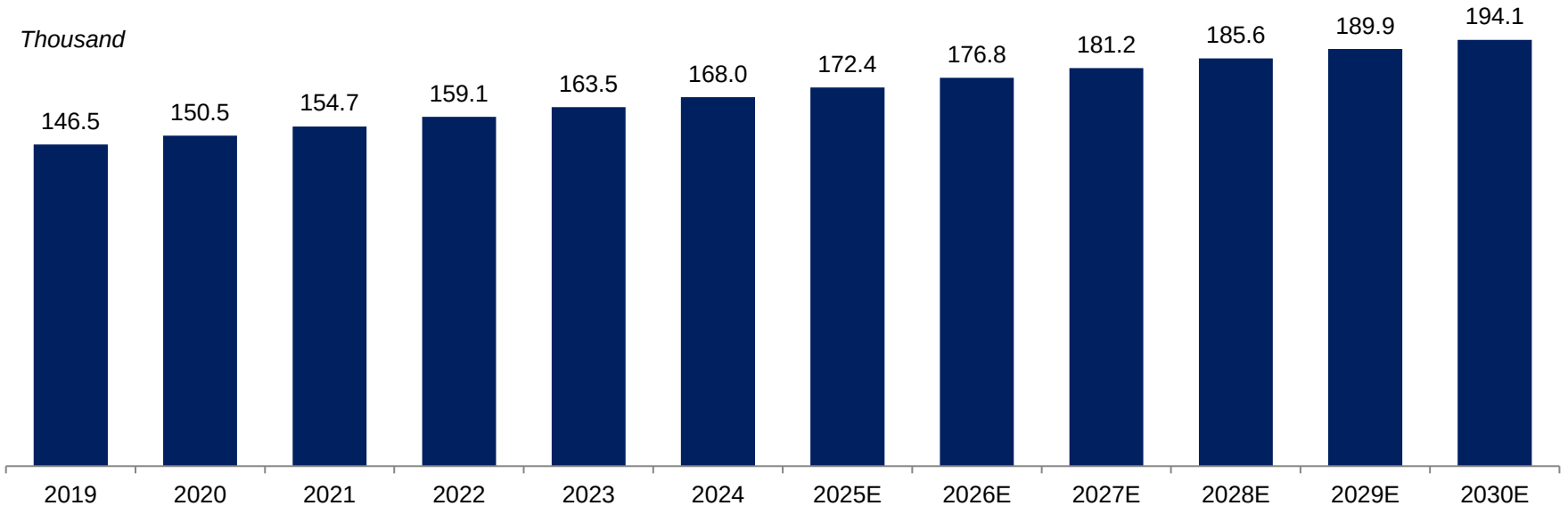
Source: Frost & Sullivan Analysis

Incidence of Small Cell Lung Cancer in China, 2019-2030E

- In China, the number of new cases of small cell lung cancer rose to 168.0 thousand in 2024, showing a CAGR of 3.5% from 2019. This figure is expected to climb further to 181.2 thousand by 2027, indicating a CAGR of 2.6% from 2024. Projections suggest that by 2030, the incidence of small cell lung cancer could reach 194.1 thousand, at a CAGR of 2.3% from 2026 to 2030.

Incidence of Small Cell Lung Cancer in China, 2019-2030E

Period	CAGR
2019-2024	2.8%
2024-2026E	2.6%
2027E-2030E	2.3%



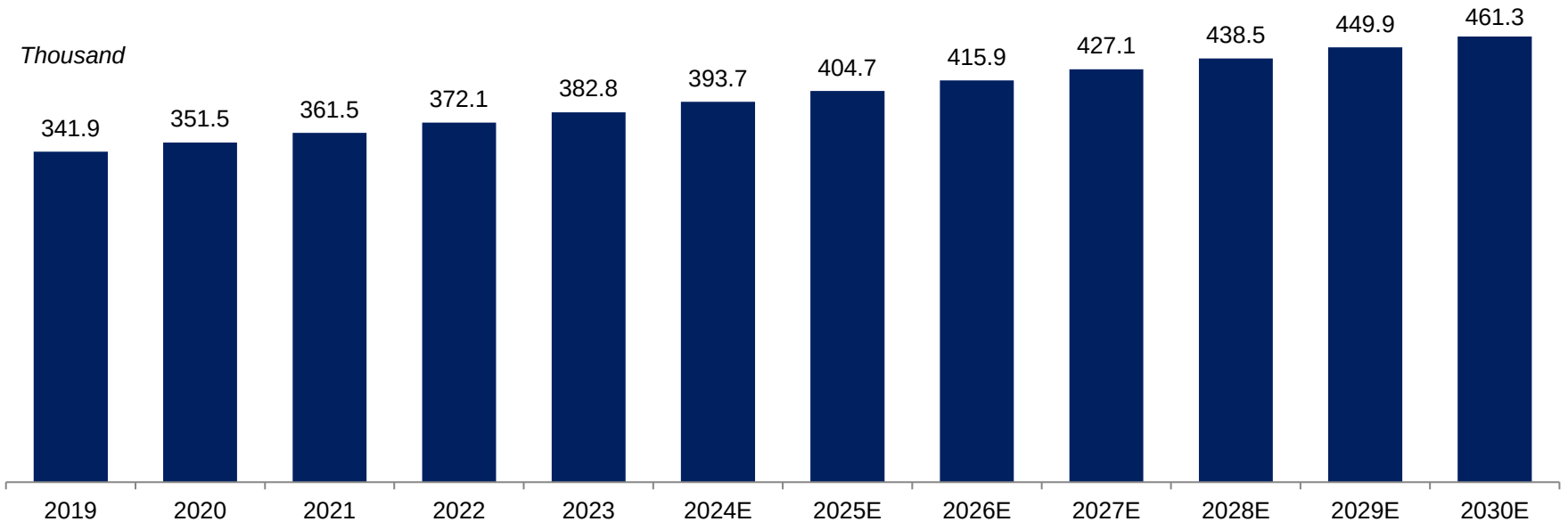
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Small Cell Lung Cancer, 2019-2030E

- The global incidence of small cell lung cancer rose from 341.9 thousand to 382.8 thousand between 2019 and 2023, showing a CAGR of 2.9%. Projections suggest that this figure will further increase to 415.9 thousand by 2026, reflecting a CAGR of 2.8% from 2023 to 2026. By 2030, it is anticipated to reach 461.3 thousand, growing at a CAGR of 2.6%.

Global Incidence of Small Cell Lung Cancer, 2019-2030E

Period	CAGR
2019-2023	2.9%
2023-2026E	2.8%
2026E-2030E	2.6%

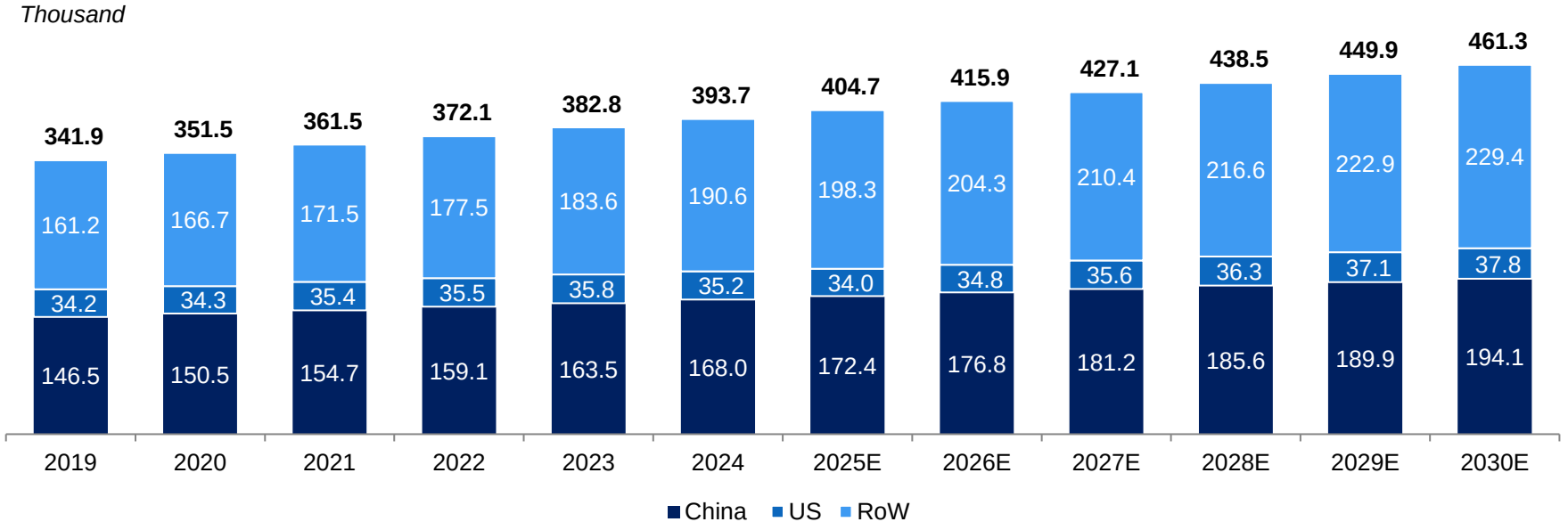


Source: IARC, Frost & Sullivan Analysis

Global Incidence of Small Cell Lung Cancer by Region, 2019-2030E

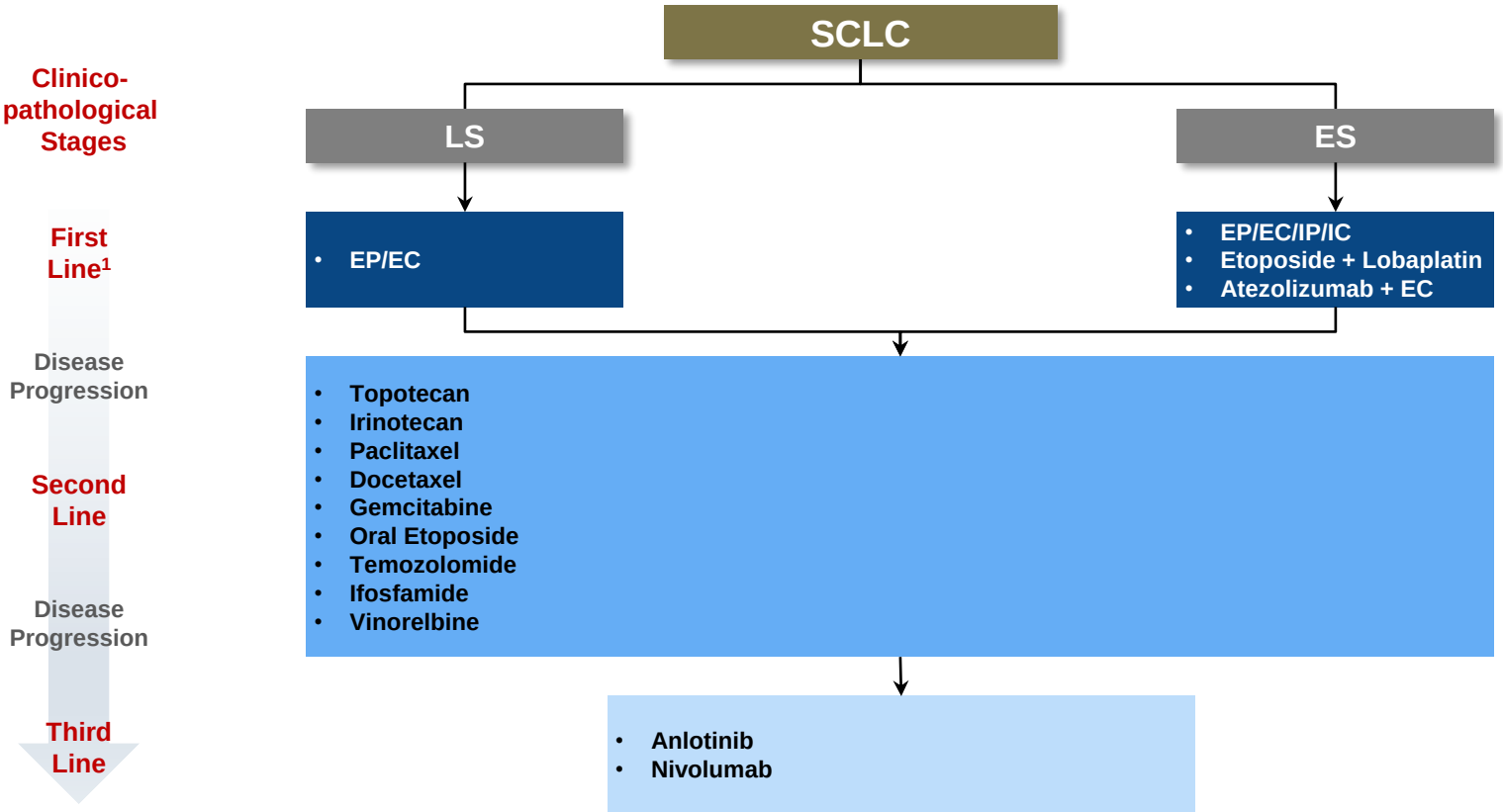
Global Incidence of Small Cell Lung Cancer by Region, 2019-2030E

Period	CAGR			
	China	US	RoW	Total
2019-2024	2.8%	0.6%	3.4%	2.9%
2024-2030E	2.4%	1.2%	3.1%	2.7%



Source: IARC, Frost & Sullivan Analysis

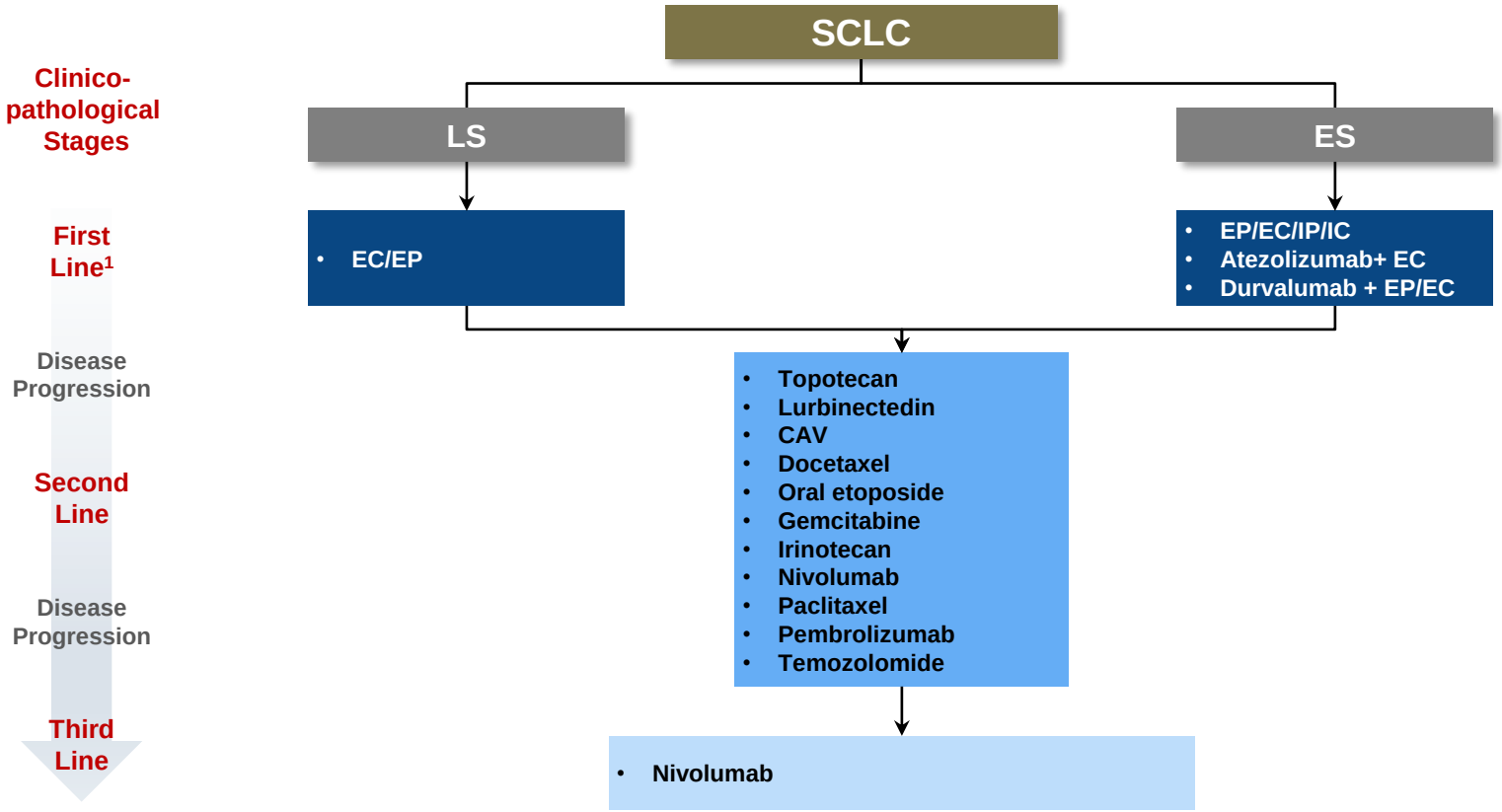
Treatment Paradigm of SCLC in China



Note: IC = Irinotecan + Carboplatin; IP = Irinotecan + Cisplatin; EC = Etoposide + Carboplatin; EP = Etoposide + Carboplati

Source: CSCO, Frost & Sullivan Analysis

Treatment Paradigm of SCLC in the US



Note: IC = Irinotecan + Carboplatin; IP = Irinotecan + Cisplatin; EC = Etoposide + Carboplatin; EP = Etoposide + Cisplatin

Source: NCCN2024, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on SCLC Approved by NMPA (2/2)

Drug Name	Brand Name	Target	Company	Indications	Approval Date
Durvalumab	英飞凡 IMFINZI	PD-L1	AstraZeneca	SCLC	2019-12-06
Toripalimab	拓益	PD-1	Junshi Biosciences Co.，Ltd.	SCLC	2018-12-17
Camrelizumab	艾瑞卡	PD-1	Hengrui Medicine Co,.Ltd.	SCLC	2019-05-29
Sintilimab	达伯舒	PD-1	Innovent Biologics Co., Ltd.	SCLC	2018-12-24
Pembrolizumab	可瑞达 Keytruda	PD-1	Merck Sharp & Dohme	SCLC	2018-07-20
Nivolumab	欧狄沃 OPDIVO	PD-1	Bristol Myers Squibb	SCLC	2018-06-15
Bevacizumab	安维汀 Avastin	VEGF	Roche	SCLC	2010-02-26

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on SCLC Approved by NMPA (1/2)

Drug Name	Brand Name	Target	Company	Indications	Approval Date
Ivonescimab	依达方	PD-1 , VEGFA	Akeso Pharmaceuticals, Inc.	SCLC	2024-05-21
Benmelstobart	安得卫	PD-L1	Chiatai Tianqing Pharmaceutical Group	SCLC	2024-04-30
adebrelimab	艾瑞利	PD-L1	Hengrui Medicine Co,.Ltd.	SCLC	2023-02-28
Serplulimab	汉斯状	PD-1	Henlius Biopharmaceutical Co.,LTD	SCLC	2022-03-22
Sugemalimab	择捷美	PD-L1	Pfizer	SCLC	2021-12-20
Penpulimab	安尼可	PD-1	Akeso / Chiatai Tianqing Pharmaceutical Group	SCLC	2021-08-03
Atezolizumab	泰圣奇 Tecentriq	PD-L1	Roche	SCLC	2020-02-11
Tislelizumab	百泽安	PD-1	Boehringer Ingelheim / BeiGene	SCLC	2019-12-26

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on SCLC Approved by FDA (1/2)

Drug Name	Brand Name	Target	Company	Indications	Approval Date
ATEZOLIZUMAB	TECENTRIQ HYBREZA	PD-L1	GENENTECH INC	SCLC	2024-09-12
TARLATAMAB	IMDELLTRA	DLL3,CD3	AMGEN INC	SCLC	2024-05-16
AMIVANTAMAB-VMJW	RYBREVANT	EGFR,MET	JANSSEN BIOTECH	SCLC	2021-05-21
CEMIPLIMAB-RWLC	LIBTAYO	PD-1	REGENERON PHARMACEUTICALS	SCLC	2018-09-28
DURVALUMAB	IMFINZI	PD-L1	ASTRAZENECA UK LTD	SCLC	2017-05-01
ATEZOLIZUMAB	TECENTRIQ	PD-L1	GENENTECH INC	SCLC	2016-05-18
NECITUMUMAB	PORTRAZZA	EGFR	ELI LILLY CO	SCLC	2015-11-24

Note: Approval date: First approval date
As of Mya 9th 2025

Source: FDA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on SCLC Approved by FDA (2/2)

Drug Name	Brand Name	Target	Company	Indications	Approval Date
NIVOLUMAB	OPDIVO	PD-1	BRISTOL MYERS SQUIBB	SCLC	2014-12-22
PEMBROLIZUMAB	KEYTRUDA	PD-1	MERCK SHARP DOHME	SCLC	2014-09-04
RAMUCIRUMAB	CYRAMZA	VEGFR2	ELI LILLY AND CO	SCLC	2014-04-21
IPILIMUMAB	YERVOY	CTLA4	BRISTOL MYERS SQUIBB	SCLC	2011-03-25
BEVACIZUMAB	AVASTIN	VEGF	ROCHE	SCLC	2004-02-26

Note: Approval date: First approval date
As of Mya 9th 2025

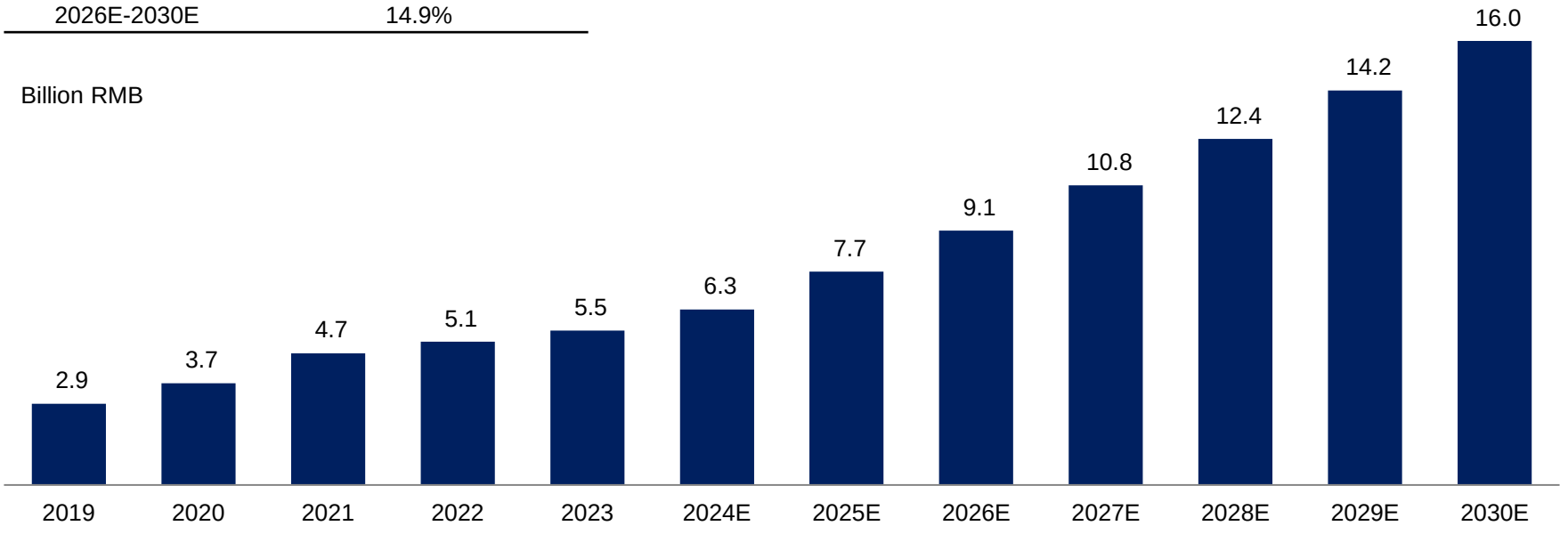
Source: FDA, Frost & Sullivan Analysis

Historical and Forecasted of China SCLC Drug Market Size, 2019-2030E

- China's SCLC drug market size reached RMB5.5 billion in 2023, with a CAGR of 17.4% from 2019 to 2023. The market size will climb to RMB9.1 billion and RMB16.0 billion in 2026 and 2030 respectively.

Historical and Forecasted of China SCLC Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	17.4%
2023-2026E	18.2%
2026E-2030E	14.9%



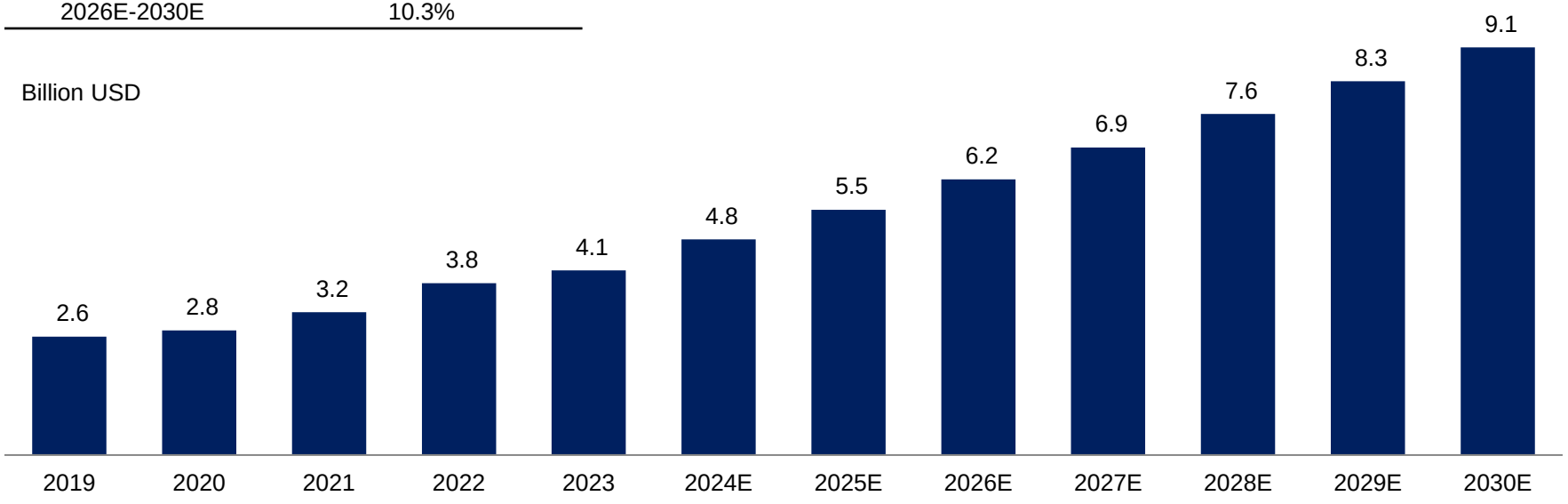
Source: Frost & Sullivan Analysis

Historical and Forecasted of Global SCLC Drug Market Size, 2019-2030E

- The global SCLC drug market size reached USD4.1 billion in 2023, with a CAGR of 11.8% from 2019 to 2023. The market size is expected to reach USD6.2 billion in 2026, with a CAGR of 14.3% from 2023 to 2026. The market will further grow to USD9.1 billion in 2030, with a CAGR of 10.3% from 2026 to 2030.

Historical and Forecasted of Global SCLC Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	11.8%
2023-2026E	14.3%
2026E-2030E	10.3%



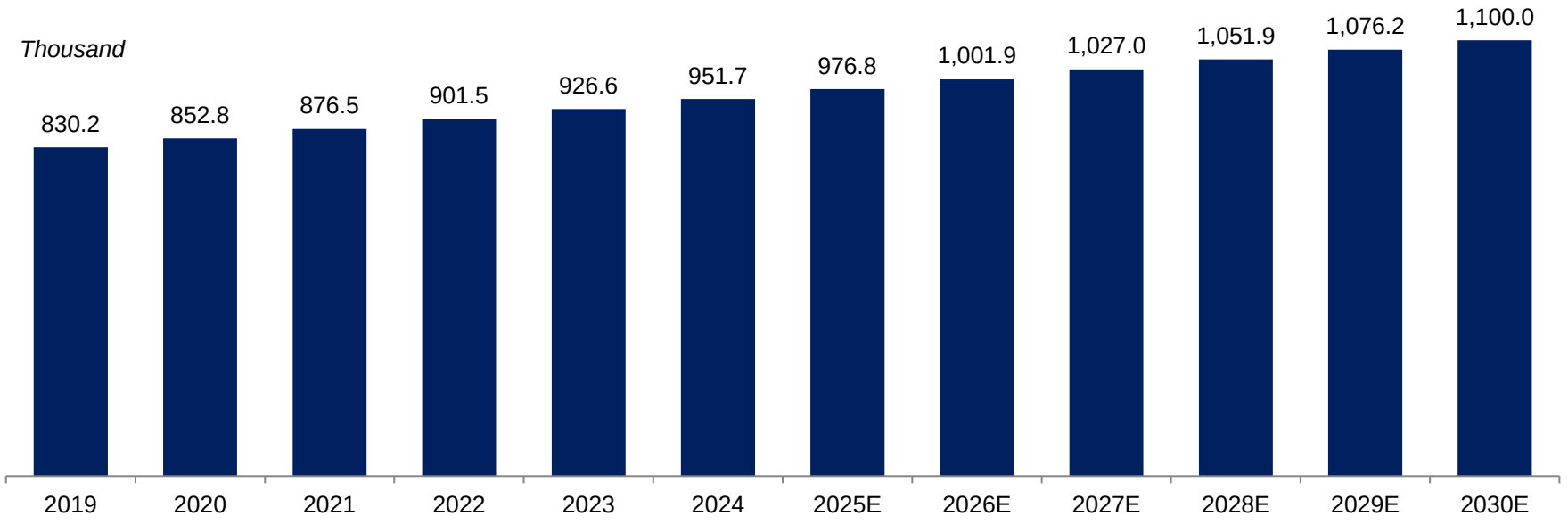
Source: Frost & Sullivan Analysis

Incidence of Non-Small Cell Lung Cancer in China, 2019-2030E

- In China, the number of new cases of non-small cell lung cancer rose to 951.7 thousand in 2024, with a CAGR of 2.8% from 2019. It is expected to continue increasing to 1,027.0 thousand by 2027, reflecting a CAGR of 2.6% from 2024. Projections indicate that by 2030, the incidence is anticipated to reach 1,100.0 thousand, at a CAGR of 2.3% from 2027 to 2030.

Incidence of Non-Small Cell Lung Cancer in China, 2019-2030E

Period	CAGR
2019-2024	2.8%
2024-2027E	2.6%
2027E-2030E	2.3%



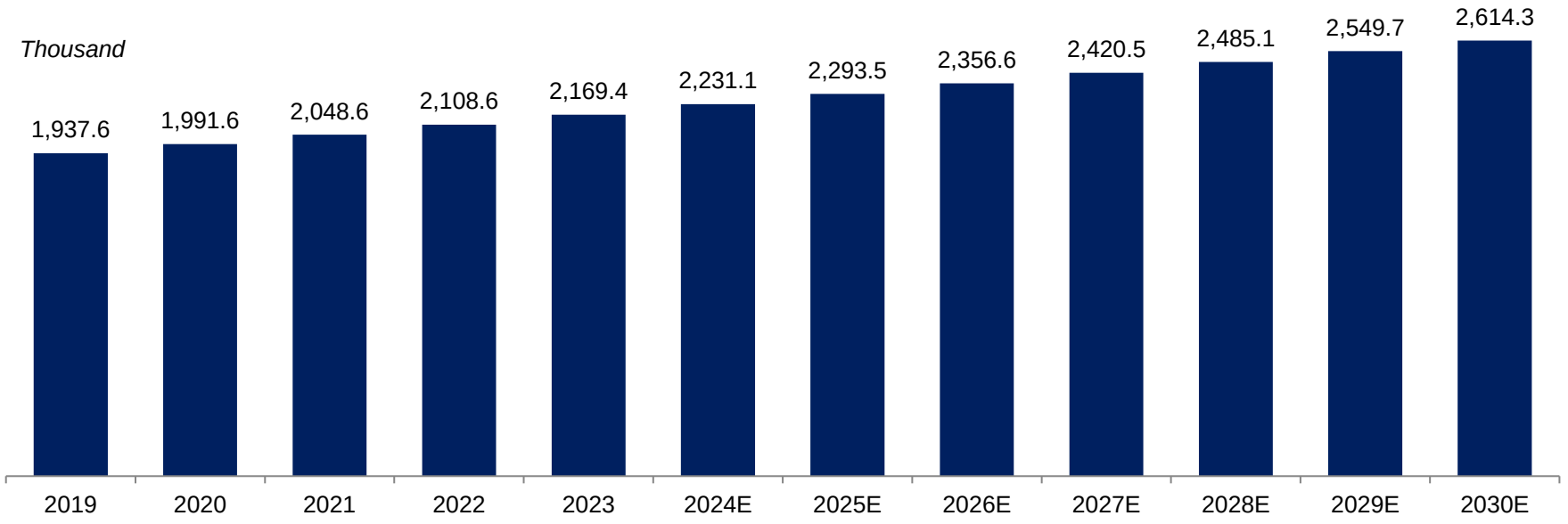
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Non-Small Cell Lung Cancer, 2019-2030E

- Between 2019 and 2023, there was an increase in the global incidence of non-small cell lung cancer from 1,937.6 thousand to 2,169.4 thousand, representing a CAGR of 2.9%. It is projected that this number will continue to rise to 2,356.6 thousand by 2026, at a CAGR of 2.8% from 2023 to 2026. By 2030, it is expected to reach 2,614.3 thousand, growing at a CAGR of 2.6%.

Global Incidence of Non-Small Cell Lung Cancer, 2019-2030E

Period	CAGR
2019-2023	2.9%
2023-2026E	2.8%
2026E-2030E	2.6%



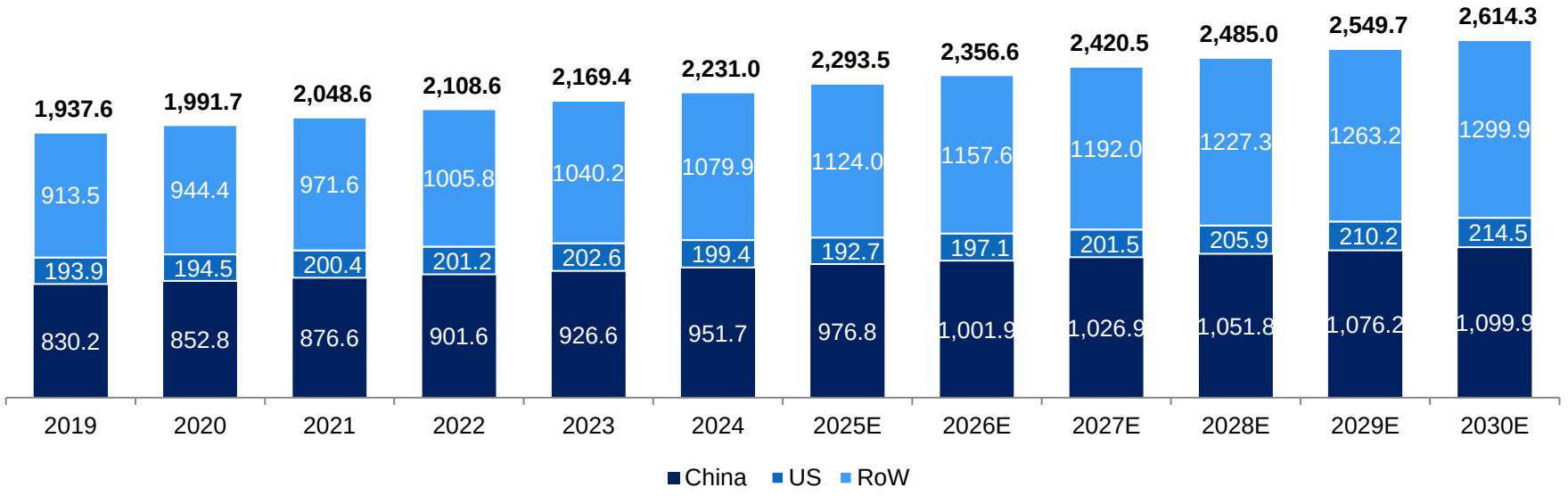
Source: IARC, Frost & Sullivan Analysis

Global Incidence of Non-Small Cell Lung Cancer by Region, 2019-2030E

Global Incidence of Non-Small Cell Lung Cancer by Region, 2019-2030E

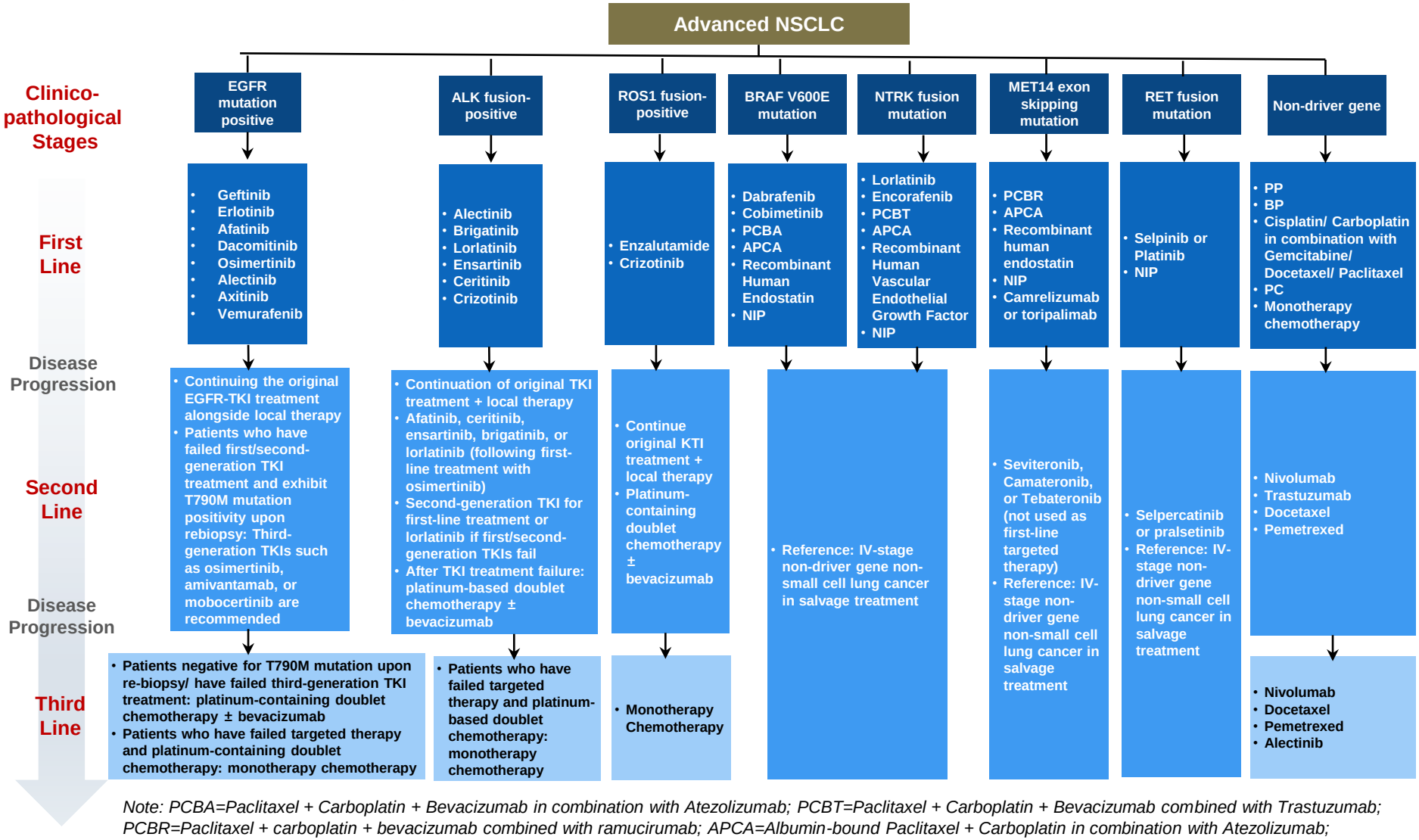
Period	CAGR			
	China	US	RoW	Total
2019-2024	2.8%	0.6%	3.4%	2.9%
2026E-2030E	2.4%	1.2%	3.1%	2.7%

Thousand



Source: IARC, Frost & Sullivan Analysis

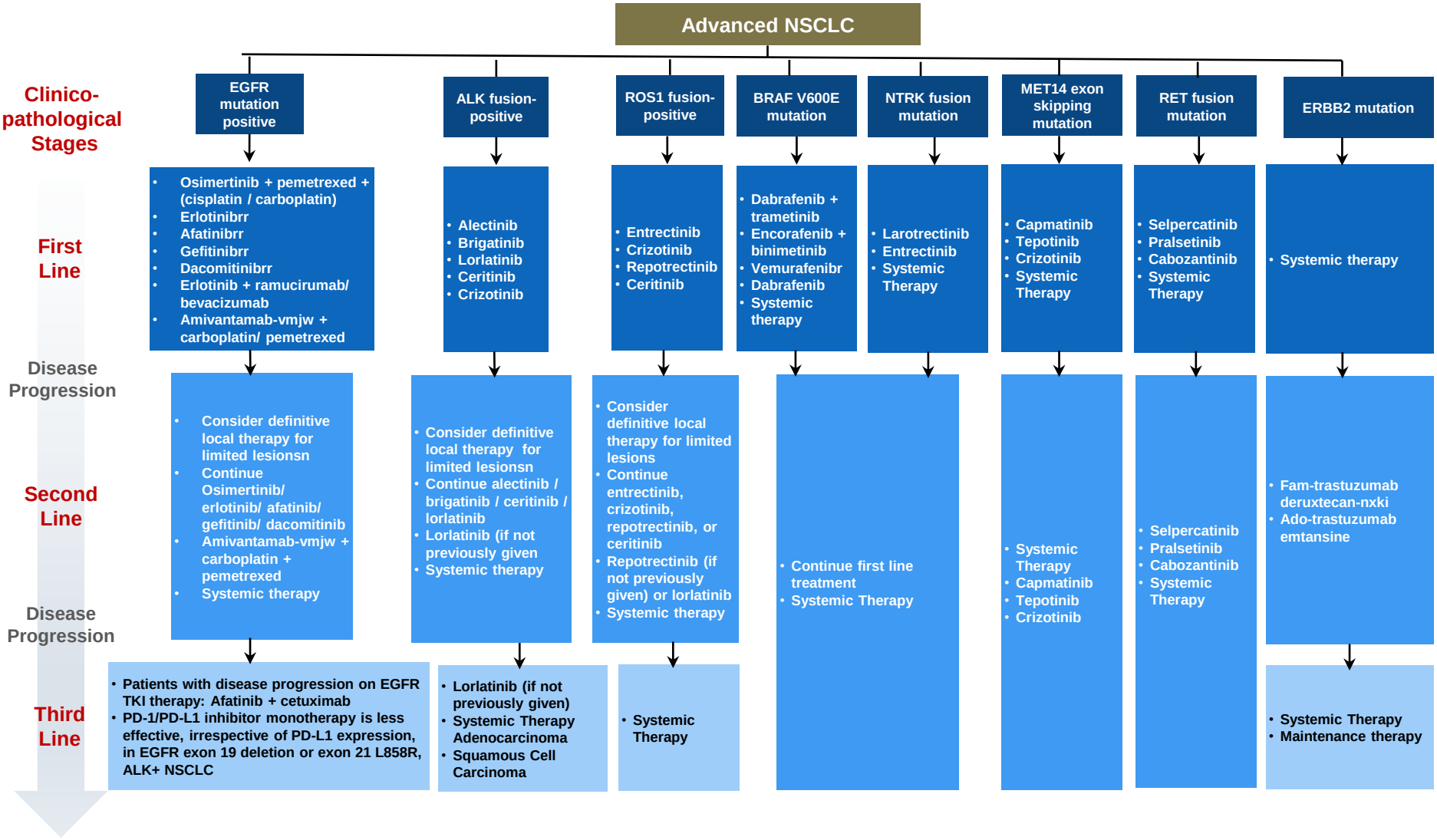
Treatment Paradigm of NSCLC in China



Note: PCBA=Paclitaxel + Carboplatin + Bevacizumab in combination with Atezolizumab; PCBT=Paclitaxel + Carboplatin + Bevacizumab combined with Trastuzumab; PCBR=Paclitaxel + carboplatin + bevacizumab combined with ramucirumab; APCA=Albumin-bound Paclitaxel + Carboplatin in combination with Atezolizumab; NIP=Nivolumab and Ipilimumab in combination with Pembrolizumab; PP=Pemetrexed in combination with platinum agents; BP=Bevacizumab in combination with platinum-based doublet chemotherapy; PC=PD-L1 inhibitors as monotherapy or in combination with chemotherapy

Source: CSCO2023, Frost & Sullivan Analysis

Treatment Paradigm of NSCLC in the US



Source: NCCN2023, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on NSCLC Approved by NMPA (1/2)

Drug Name	Brand Name	Target	Company	Indication	Approval Date
Amivantamab	锐珂	EGFR , c-Met	Janssen-Cilag International NV	NSCLC	2025-02-08
Ivonescimab	依达方	PD-1 , VEGFA	Akeso Pharmaceuticals, Inc.	NSCLC	2024-05-21
Serplulimab	汉斯状	PD-1	Henlius Biopharmaceutical Co.,LTD	NSCLC	2022-03-22
Sugemalimab	择捷美	PD-L1	Pfizer	NSCLC	2021-12-20
Penpulimab	安尼可	PD-1	Akeso / Chiatai Tianqing Pharmaceutical Group	NSCLC	2021-08-03
Atezolizumab	泰圣奇 Tecentriq	PD-L1	Roche	NSCLC	2020-02-11
Tislelizumab	百泽安	PD-1	Boehringer Ingelheim / BeiGene	NSCLC	2019-12-26
Durvalumab	英飞凡 IMFINZI	PD-L1	AstraZeneca	NSCLC	2019-12-06

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on NSCLC Approved by NMPA (2/2)

Drug Name	Brand Name	Target	Company	Indication	Approval Date
Toripalimab	拓益	PD-1	Junshi Biosciences Co.，Ltd.	NSCLC	2018-12-17
Camrelizumab	艾瑞卡	PD-1	Hengrui Medicine Co,.Ltd.	NSCLC	2019-05-29
Sintilimab	达伯舒	PD-1	Innovent Biologics Co., Ltd.	NSCLC	2018-12-24
Pembrolizumab	可瑞达 Keytruda	PD-1	Merck Sharp & Dohme	NSCLC	2018-07-20
Nivolumab	欧狄沃 OPDIVO	PD-1	Bristol Myers Squibb	NSCLC	2018-06-15
Bevacizumab	安维汀 Avastin	VEGF	Roche	NSCLC	2010-02-26

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on NSCLC Approved by FDA (1/2)

Drug Name	Brand Name	Target	Company	Indications	Approval Date
ZENOCUTUZUMAB	BIZENGRI	HER2,HER3	Merus	NSCLC	2024-12-4
AMIVANTAMAB-VMJW	RYBREVANT	EGFR,MET	JANSSEN BIOTECH	NSCLC	2021-05-21
CEMIPLIMAB-RWLC	LIBTAYO	PD-1	REGENERON PHARMACEUTICALS	NSCLC	2018-09-28
DURVALUMAB	IMFINZI	PD-L1	ASTRAZENECA UK LTD	NSCLC	2017-05-01
ATEZOLIZUMAB	TECENTRIQ	PD-L1	GENENTECH INC	NSCLC	2016-05-18
NECITUMUMAB	PORTRAZZA	EGFR	ELI LILLY CO	NSCLC	2015-11-24

Note: Approval date: First approval date
As of Mya 9th 2025

Source: FDA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on NSCLC Approved by FDA (2/2)

Drug Name	Brand Name	Target	Company	Indications	Approval Date
NIVOLUMAB	OPDIVO	PD-1	BRISTOL MYERS SQUIBB	NSCLC	2014-12-22
PEMBROLIZUMAB	KEYTRUDA	PD-1	MERCK SHARP DOHME	NSCLC	2014-09-04
RAMUCIRUMAB	CYRAMZA	VEGFR2	ELI LILLY AND CO	NSCLC	2014-04-21
IPILIMUMAB	YERVOY	CTLA4	BRISTOL MYERS SQUIBB	NSCLC	2011-03-25
BEVACIZUMAB	AVASTIN	VEGF	ROCHE	NSCLC	2004-02-26

Note: Approval date: First approval date
As of Mya 9th 2025

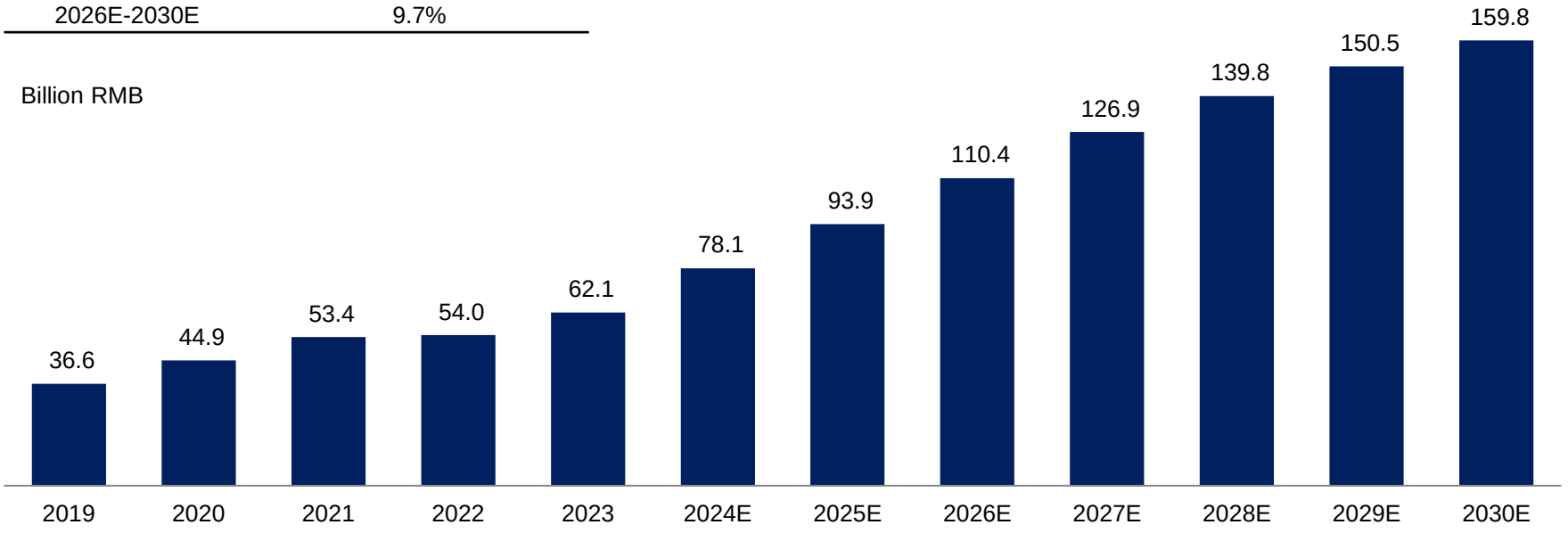
Source: FDA, Frost & Sullivan Analysis

Historical and Forecasted of China NSCLC Drug Market Size, 2019-2030E

- China's NSCLC drug market size reached RMB62.1 billion in 2023, with a CAGR of 14.2% from 2019 to 2023. The market size will climb to RMB110.4 billion and RMB159.8 billion in 2026 and 2030 respectively.

Historical and Forecasted of China NSCLC Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	14.2%
2023-2026E	21.1%
2026E-2030E	9.7%



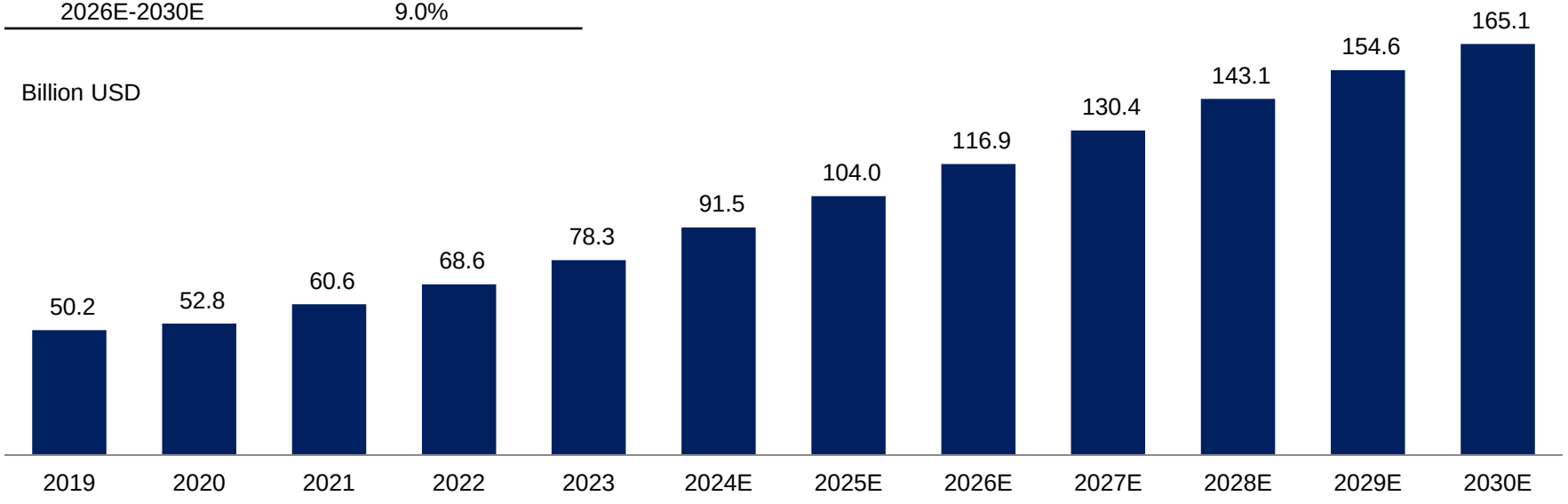
Source: Frost & Sullivan Analysis

Historical and Forecasted of Global NSCLC Drug Market Size, 2019-2030E

- The global NSCLC drug market size reached USD78.3 billion in 2023, with a CAGR of 11.8% from 2019 to 2023. The market size is expected to reach USD116.9 billion in 2026, with a CAGR of 14.3% from 2023 to 2026. The market will further grow to USD165.1 billion in 2030, with a CAGR of 9.0% from 2026 to 2030.

Historical and Forecasted of Global NSCLC Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	11.8%
2023-2026E	14.3%
2026E-2030E	9.0%



Source: Frost & Sullivan Analysis

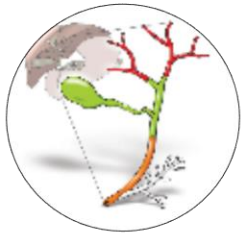
Overview of Cholangiocarcinoma

Symptoms, Risk Factors, Pathogenesis and Survival Rate

- Cholangiocarcinoma (CCA), also known as bile duct cancer, is a rare disease in which malignant cells form in the bile ducts, the branched tubes that connect the liver and gallbladder to the small intestine.
- Common signs of bile duct cancer include jaundice , fatigue and pain in the abdomen, and the risk factors of CCA usually point to a common role chronic biliary inflammation in CCA development.
- iCCA is sometimes misdiagnosed as Hepatocellular carcinoma (HCC). Considering this typical vascular pattern for HCC, contrast-enhanced ultrasound (CEUS) misdiagnosed as HCC a significantly higher number of ICC than CT (52% vs. 4.2%, P = 0.004) and MRI (52% vs. 9.1%, P = 0.02).

Symptoms

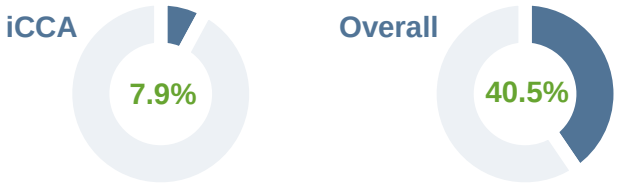
- Pruritus
- Painless obstructive jaundice
- Vague abdominal pain
- Anorexia
- Distended gallbladder
- Fatigue



Cholangiocarcinoma do not usually cause any symptoms in the early stage, but often result when bile ducts become blocked by the tumor.

Survival Rate

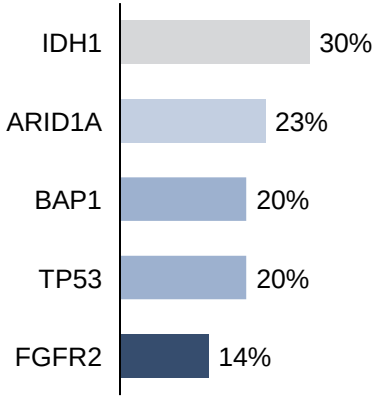
Currently, there is no direct assay for early detection of CCA. Hence, the CCA patients are normally found at the late stage of cancer with low survival rate. In the China, the five-year survival rate for iCCA is 7.9%, which is lower than the five-year survival rate of all cancer types combined at 43.7%. In the USA, the five-year survival rate for iCCA and eCCA are 9% and 11% respectively, which are lower than the five-year survival rate of all cancer types combined at 69%.



Molecular and genetic pathogenesis

- With the research goes deeper, it reveals the involvement of molecular pathways in development of CCA. In specific, the pathways include genetic mutations, chromosomal changes, aberrant epigenetic landscapes, microRNAs dysregulation, etc.
- For example, gene fusions (e.g. ROS or FGFR) resulting from chromosomal rearrangement are one of the most common events considered contributing to cancer development of CCA.

Gene alterations distribution in intrahepatic CCA



- The most commonly altered genes in intrahepatic cholangiocarcinoma (iCCA) were IDH1 (30%), ARID1A (23%) BAP1 (20%), TP53 (20%) and FGFR2 gene fusions (14%).
- FGFR Alterations (including fusion and rearrangement, point mutation, gene amplification) are observed in 25.2% of CCA patients, and FGFR fusions and rearrangements are observed in 7.4% of CCA patients.

Source: Literature Review, Frost & Sullivan Analysis

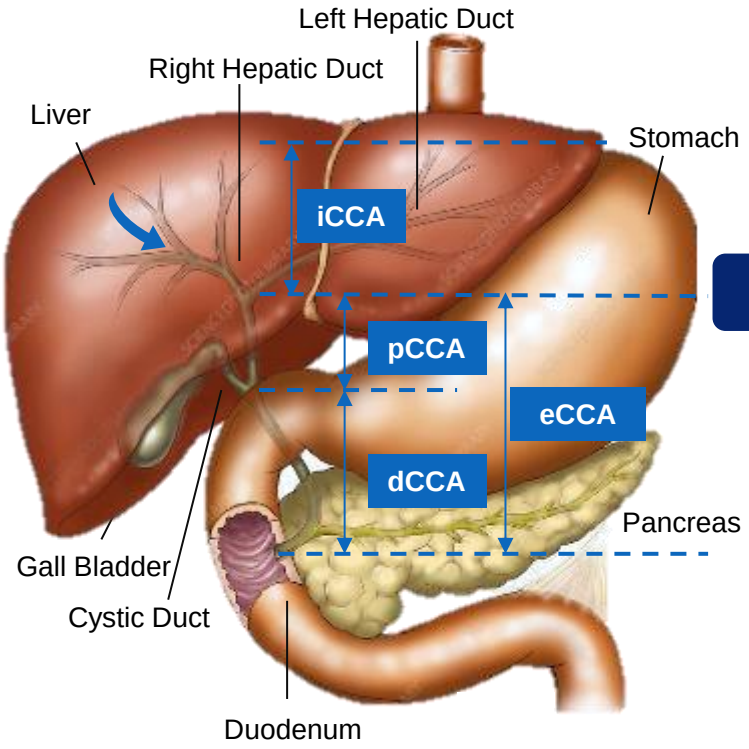
Overview of Cholangiocarcinoma (CCA)

Classification

- Cholangiocarcinomas (CCAs) are tumors that develop along the bile duct. Depending on their sites of origin, CCA can be categorized into intrahepatic (iCCA) and extrahepatic cholangiocarcinoma (eCCA), with the later further divided into perihilar and distal CCA, abbreviated as pCCA and dCCA, respectively.
- Biliary tract cancers (BTC) represent the second most common type of hepatobiliary cancer worldwide, and are typically consist of CCAs and gallbladder carcinoma (GBC). BTC typically present at an advanced stage and are resectable in less than 30% of cases, often characterized by a poor prognosis.

Bile Duct Anatomy

- Liver cells make bile. Bile flows into small channels (bile canaliculi) that converge into thin tubes called ducts.
- These ducts form larger channels that flow into **left and right hepatic ducts**.
- The duct connected to the gallbladder is called **cystic duct**.
- They join to carry the bile to the first part of the small intestine called the **duodenum**.



Classification of Cholangiocarcinoma

- **CCA**
  - **Intrahepatic CCA (20%)**
    - Intrahepatic CCA (iCCA) occurs in the parts of the bile ducts within the liver.
  - **Extrahepatic CCA (80%)**
    - Extrahepatic CCA (eCCA) is found outside the liver.
    - **pCCA (50%)**
      - Perihilar CCA (pCCA) occurs in the bile ducts just outside of the liver, from the joint of left and right hepatic duct to the site above cystic origin.
    - **dCCA (30%)**
      - Distal CCA (dCCA) occurs in the portion of the bile duct nearest the small intestine.

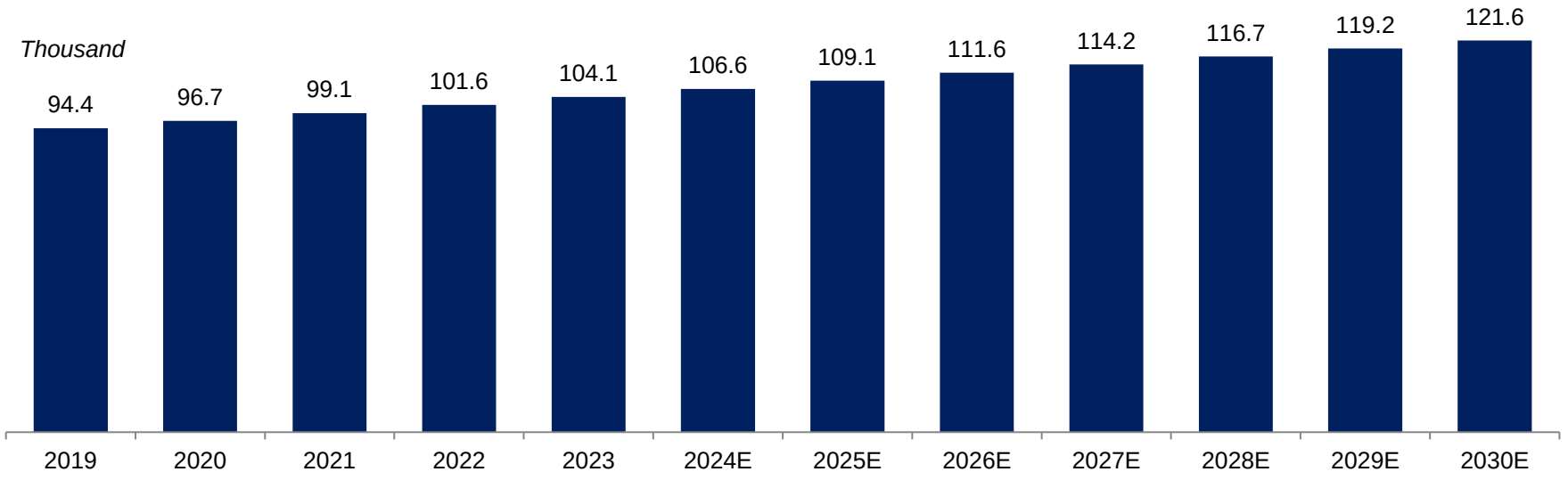
Source: Literature Review, Frost & Sullivan Analysis

Incidence of Cholangiocarcinoma in China, 2019-2030E

- In China, new case of cholangiocarcinoma reached 104.1 thousand in 2023 at a CAGR of 2.5% from 2019. It is projected to further increase to 111.6 thousand in 2026, representing a CAGR of 2.4% from 2023. It is estimated that the incidence would achieve 121.6 thousand in 2030, representing a CAGR of 2.2% from 2026 to 2030.

Incidence of Cholangiocarcinoma in China, 2019-2030E

Period	CAGR
2019-2023	2.5%
2023-2026E	2.4%
2026E-2030E	2.2%



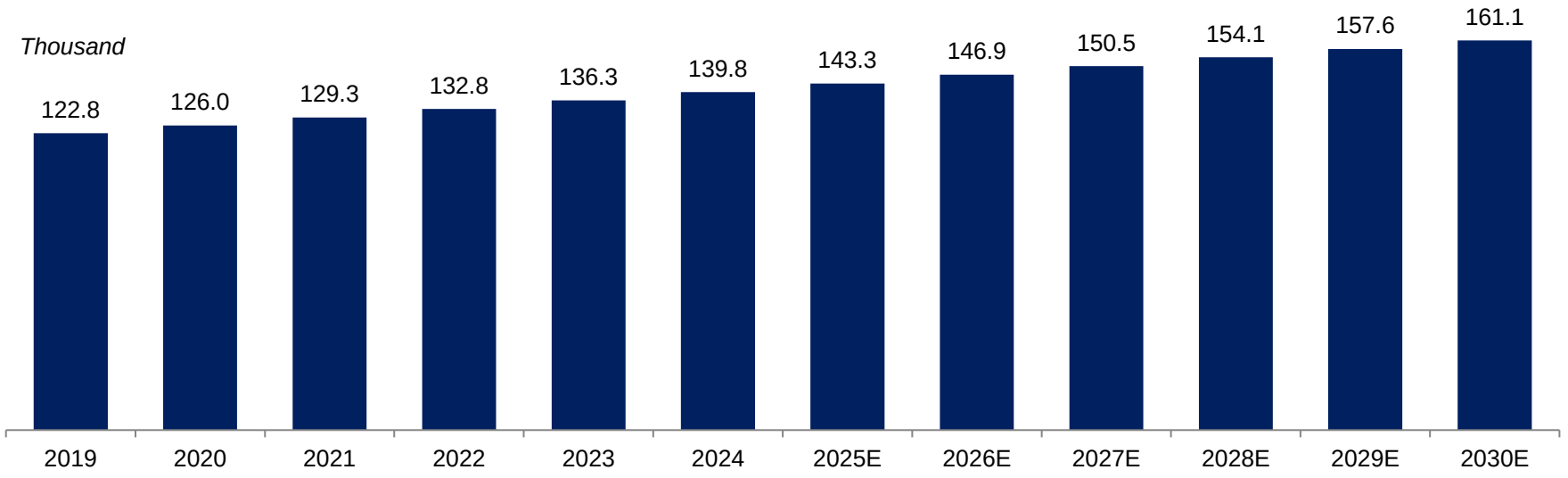
Source: NCCR, Frost & Sullivan Analysis

Incidence of Biliary Tract Cancer in China, 2019-2030E

- In China, new case of BTC reached 139.8 thousand in 2024 at a CAGR of 2.6% from 2019. It is projected to further increase to 150.5 thousand in 2027, representing a CAGR of 2.5% from 2024. It is estimated that the incidence would achieve 161.1 thousand in 2030, representing a CAGR of 2.3% from 2026 to 2030.

Incidence of Biliary Tract Cancer in China, 2019-2030E

Period	CAGR
2019-2024	2.6%
2024-2027E	2.5%
2027E-2030E	2.3%



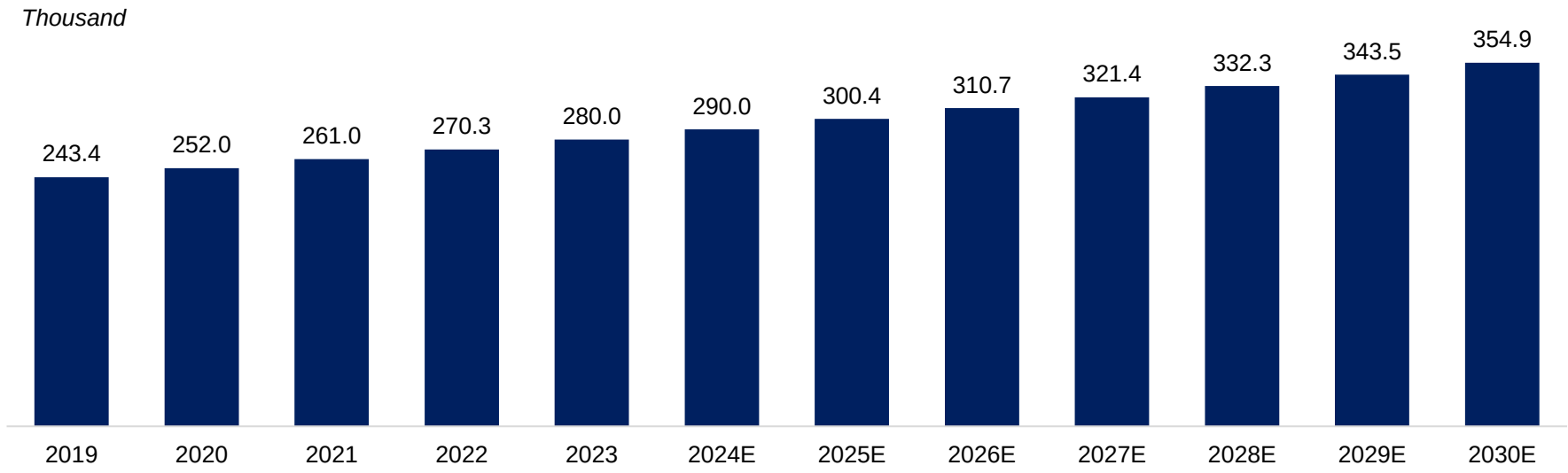
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Cholangiocarcinoma, 2019-2030E

- Incidence number of CCA around the world increased from 243.4 thousand to 280.0 thousand in 2019 and 2023. The number is expected to grow to 310.7 thousand in 2026 at a CAGR of 3.5% from 2023 to 2026. The number is expected to grow to 354.9 thousand in 2030, at a CAGR of 3.4%.

Global Incidence of Cholangiocarcinoma, 2019-2030E

Period	CAGR
2019-2023	3.6%
2023-2026E	3.5%
2026E-2030E	3.4%



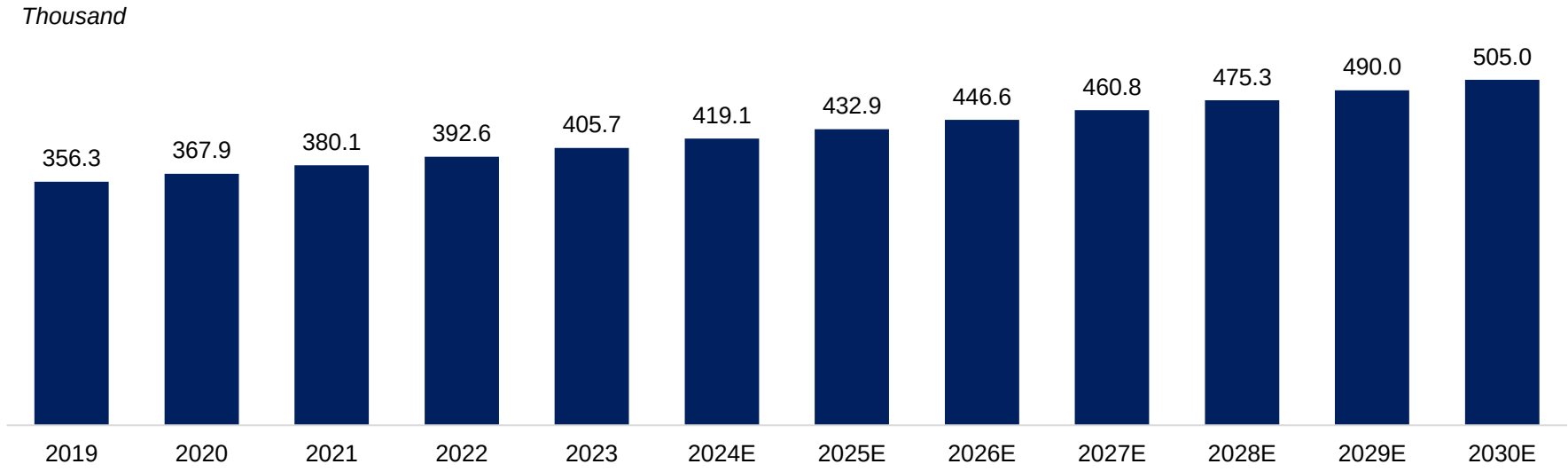
Source: IARC, Frost & Sullivan Analysis

Global Incidence of Biliary Tract Cancer, 2019-2030E

- Incidence number of BTC around the world increased from 356.3 thousand to 405.7 thousand in 2019 and 2023. The number is expected to grow to 446.6 thousand in 2026 at a CAGR of 3.3% from 2023 to 2026. The number is expected to grow to 505.0 thousand in 2030, at a CAGR of 3.1%.

Global Incidence of Biliary Tract Cancer, 2019-2030E

Period	CAGR
2019-2023	3.3%
2023-2026E	3.3%
2026E-2030E	3.1%

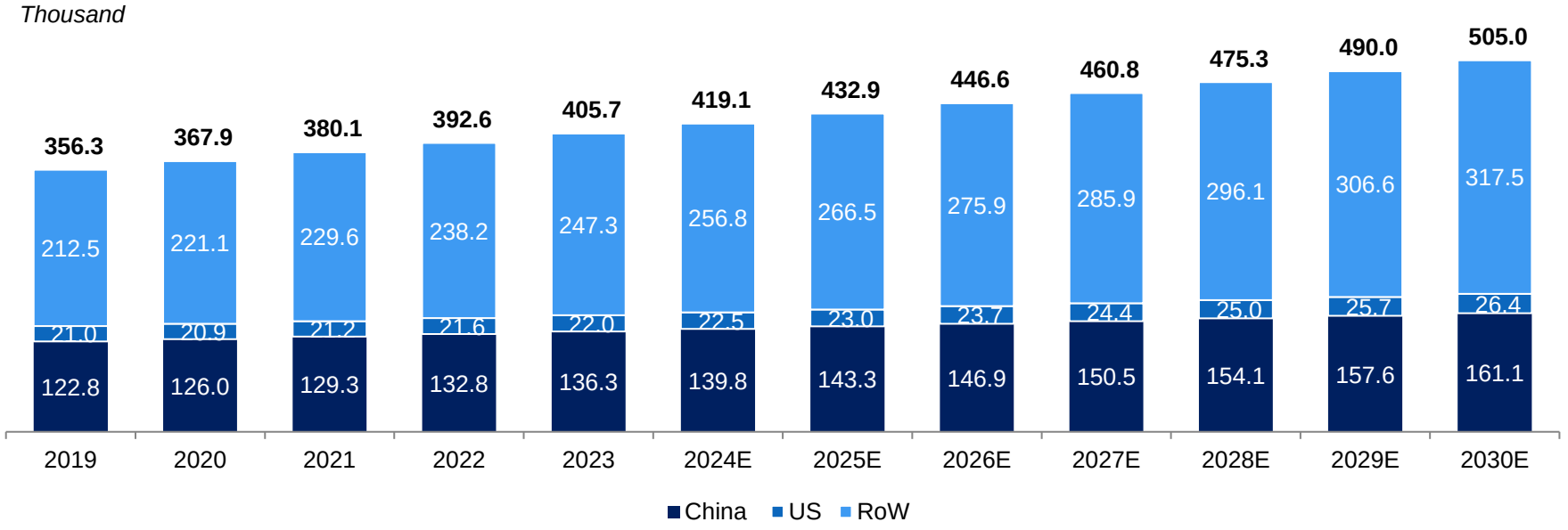


Source: IARC, Frost & Sullivan Analysis

Global Incidence of Biliary Tract Cancer by Region, 2019-2030E

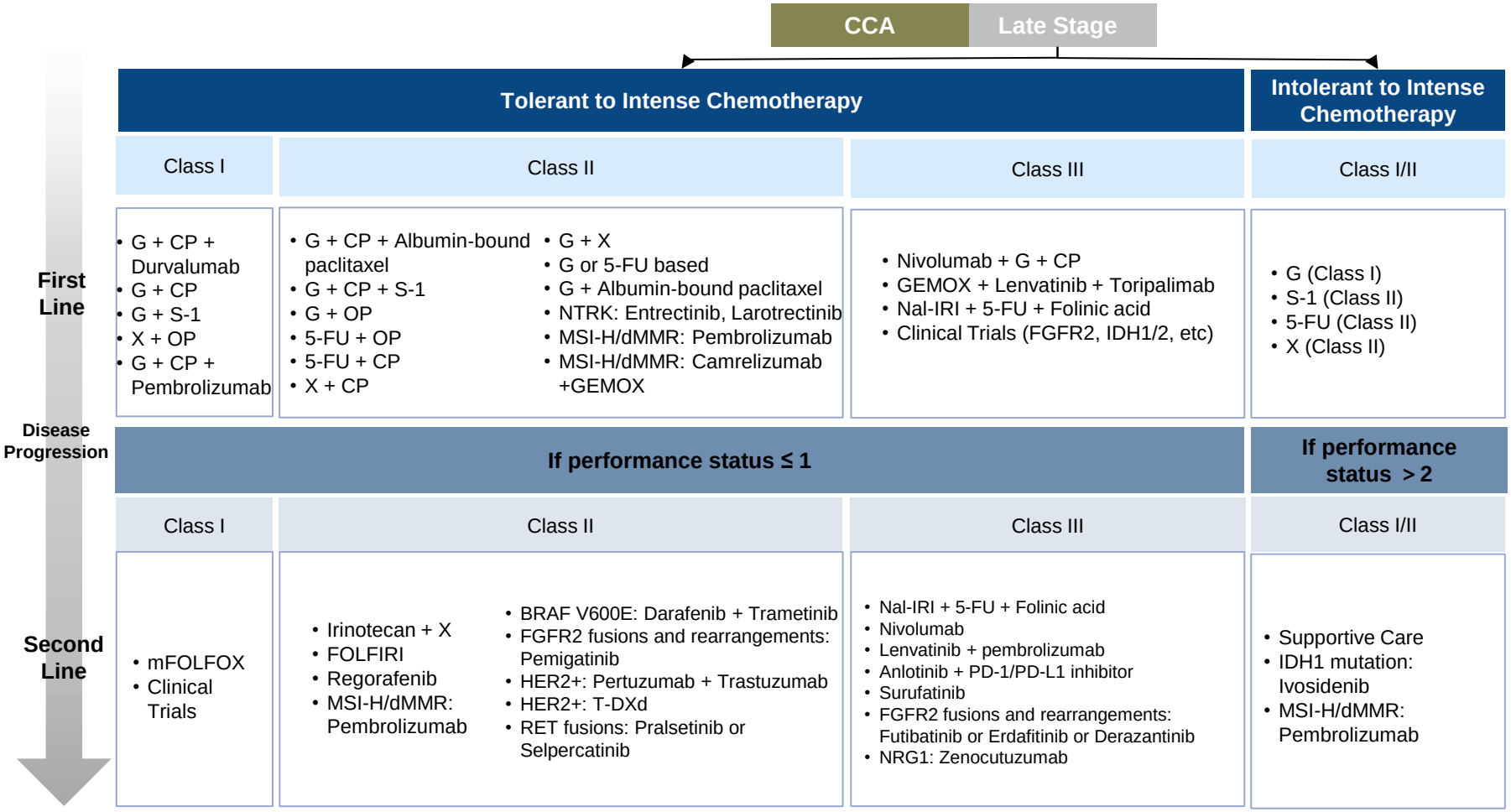
Global Incidence of Biliary Tract Cancer by Region, 2019-2030E

Period	CAGR			
	China	US	RoW	Total
2019-2024	2.6%	1.4%	3.9%	3.3%
2024-2030E	2.4%	2.7%	3.6%	3.2%



Source: IARC, Frost & Sullivan Analysis

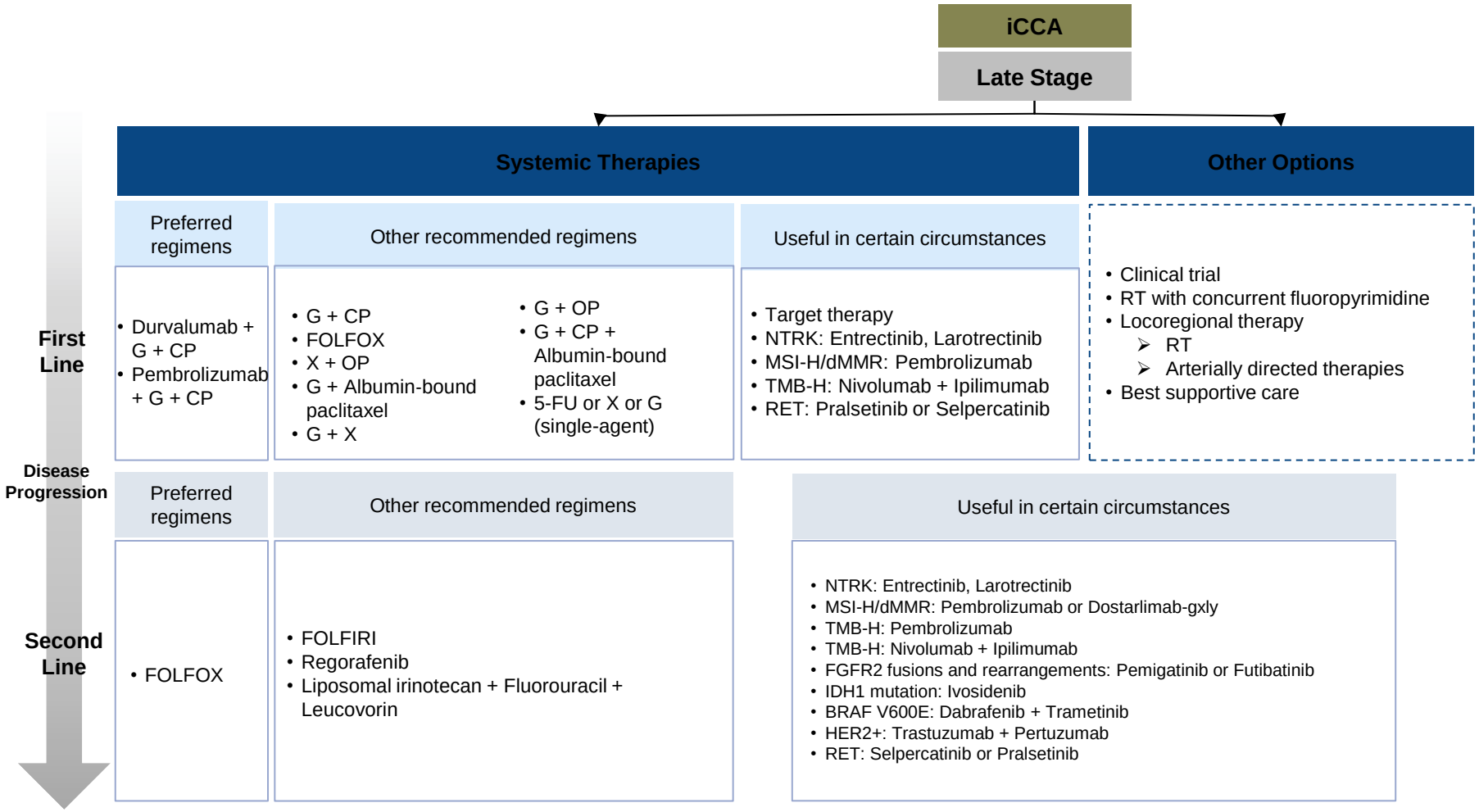
Treatment Paradigm of CCA in China



Note: G = Gemcitabine; CP = Cisplatin; S-1 = Tegafur/Gimeracil/Oteracil; OP = Oxaliplatin, X = Capecitabine; 5-FU = 5-Fluorouracil; mFOLFOX = Oxaliplatin + 5-Fluorouracil; FOLFIRI = Folinic acid, Fluorouracil and Irinotecan; T-DXd = Trastuzumab Deruxtecan

Source: CSCO2023, Frost & Sullivan Analysis

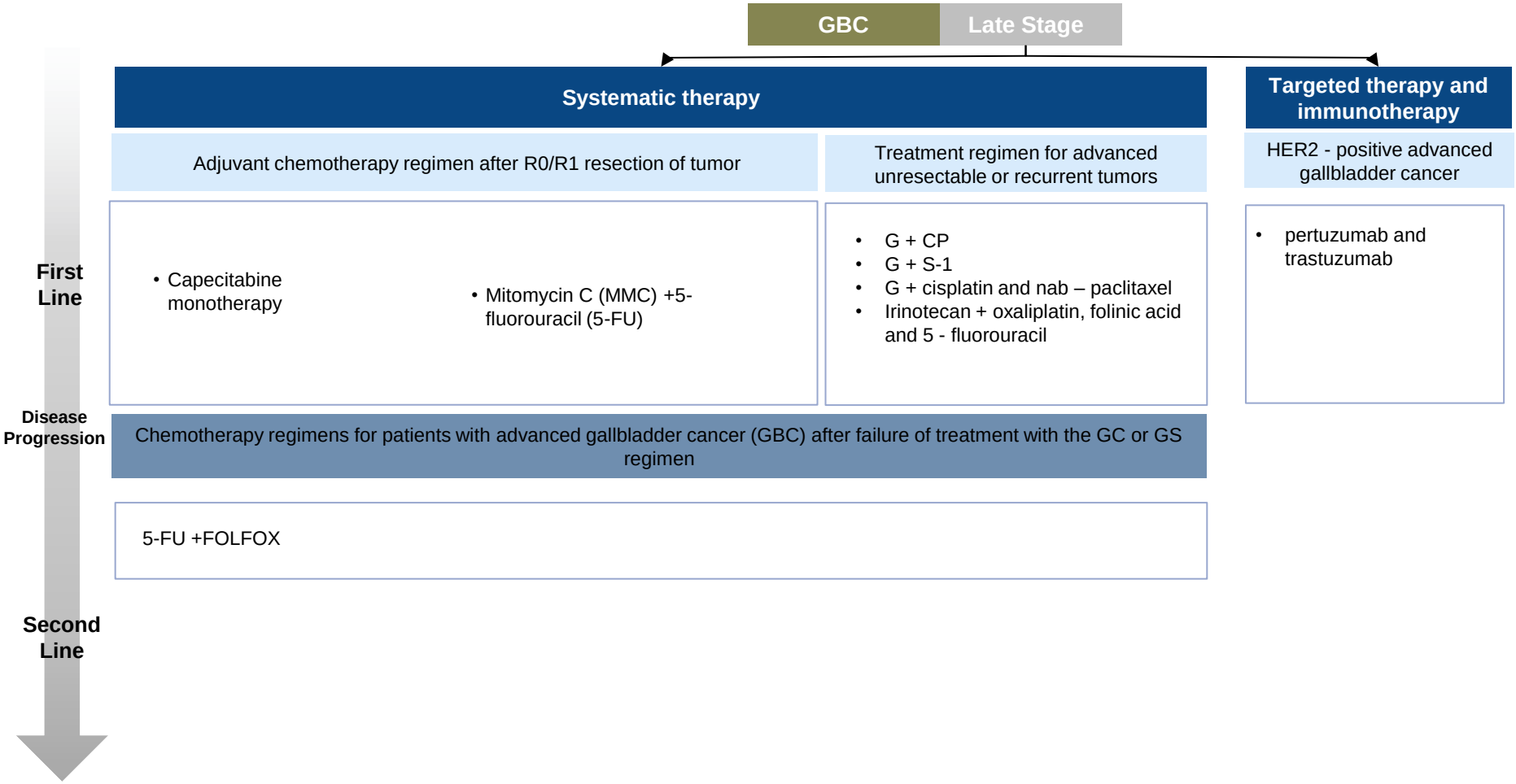
Treatment Paradigm of iCCA in the US



Note: G = Gemcitabine; CP = Cisplatin; OP = Oxaliplatin, X = Capecitabine; 5-FU = 5-Fluorouracil; FOLFOX = Oxaliplatin + 5-Fluorouracil; FOLFIRI = Folinic acid, Fluorouracil and Irinotecan; T-DXd = Trastuzumab Deruxtecan

Source: NCCN2023 V3, Frost & Sullivan Analysis

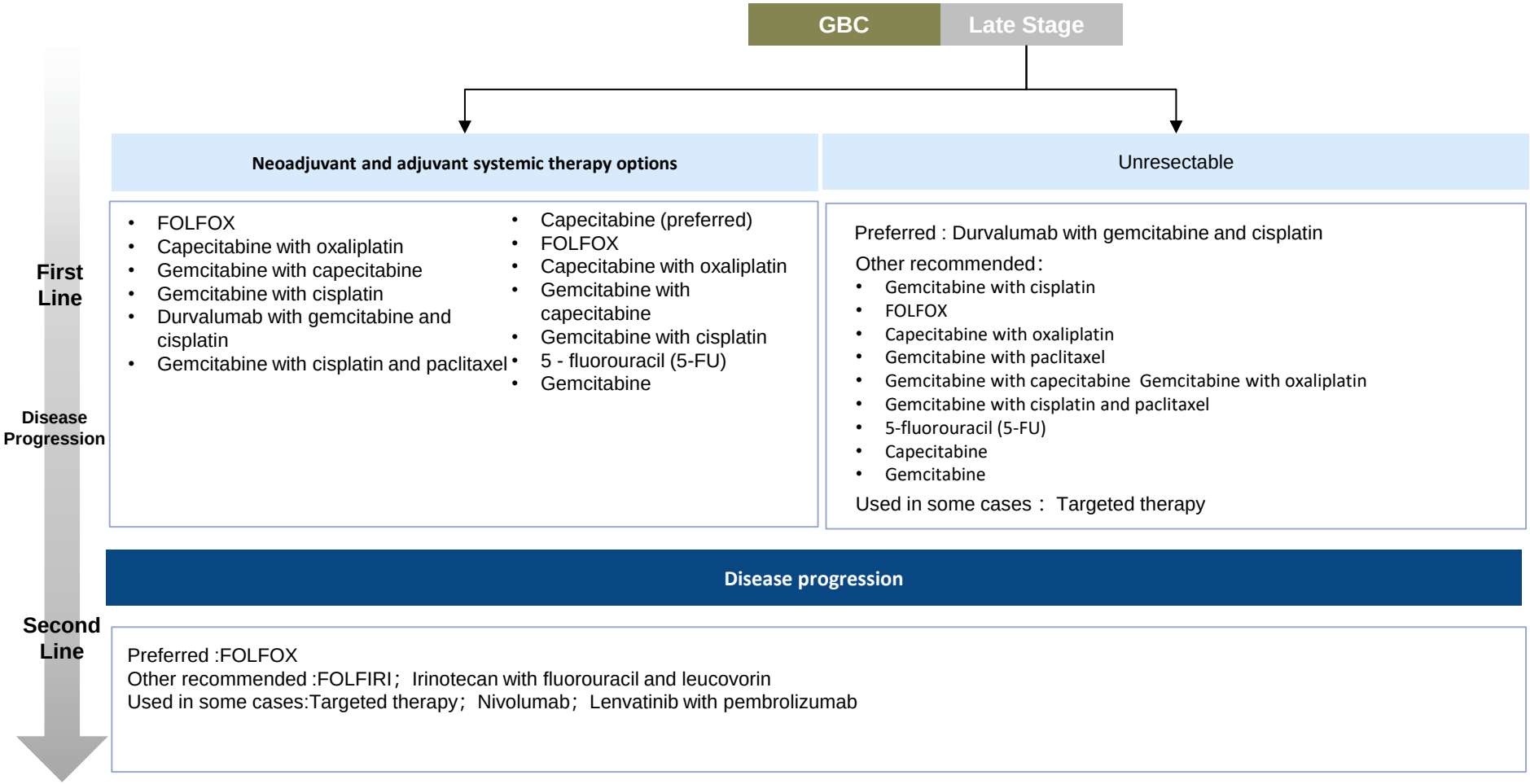
Treatment Paradigm of GBC in China



Note: G = Gemcitabine; CP = Cisplatin; S-1 = Tegafur/Gimeracil/Oteracil; OP = Oxaliplatin, X = Capecitabine; 5-FU = 5-Fluorouracil; mFOLFOX = Oxaliplatin + 5-Fluorouracil; FOLFIRI = Folinic acid, Fluorouracil and Irinotecan; T-DXd = Trastuzumab Deruxtecan

Source: CSCO2023, Frost & Sullivan Analysis

Treatment Paradigm of GBC in US

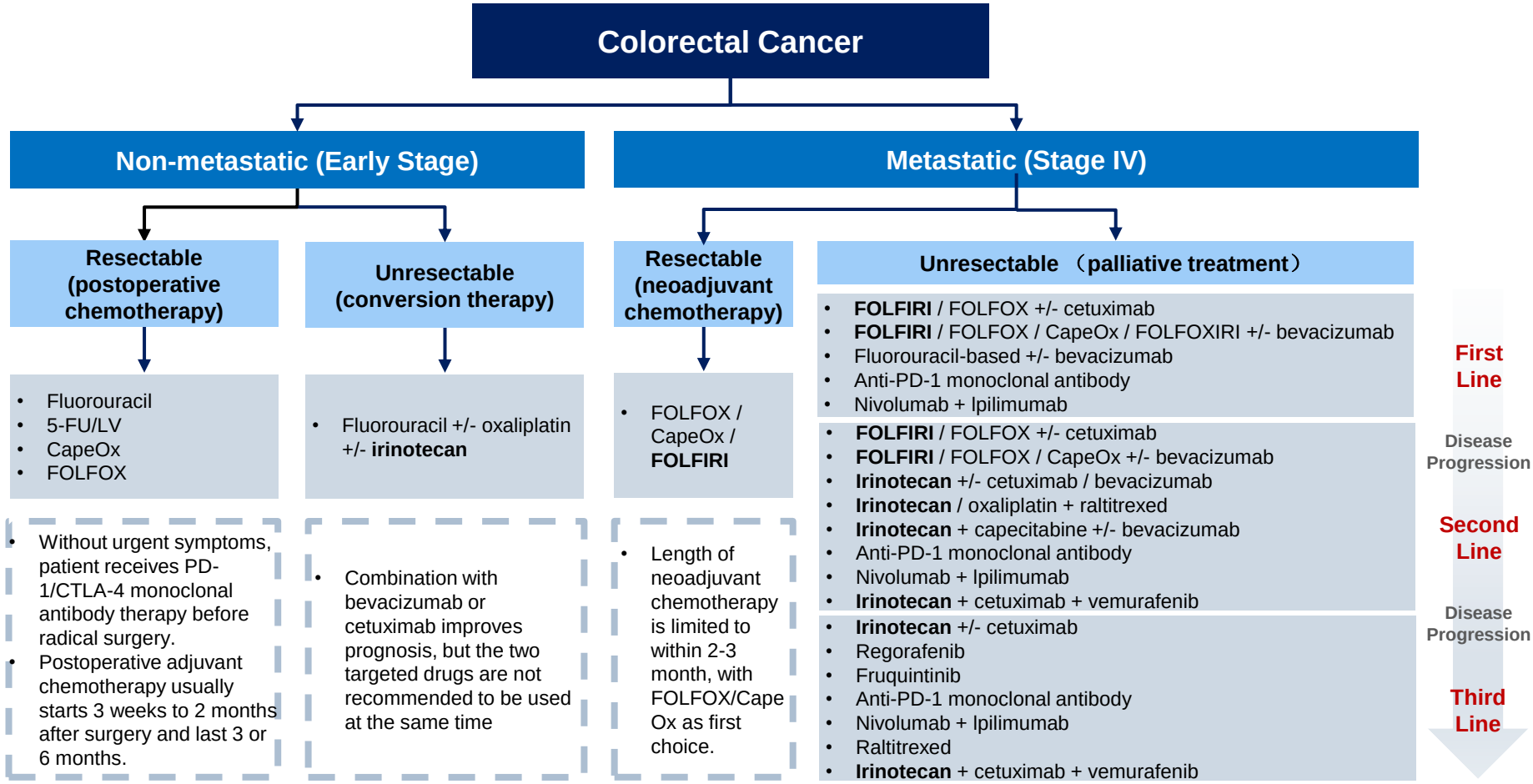


Note: G = Gemcitabine; CP = Cisplatin; S-1 = Tegafur/Gimeracil/Oteracil; OP = Oxaliplatin, X = Capecitabine; 5-FU = 5-Fluorouracil; mFOLFOX = Oxaliplatin + 5-Fluorouracil; FOLFIRI = Folinic acid, Fluorouracil and Irinotecan; T-DXd = Trastuzumab Deruxtecan

Source: CSCO2023, Frost & Sullivan Analysis

Treatment Paradigm of GBD in China

- In China, CSCO guideline on colorectal cancer recommends using CPT analogue drug (irinotecan) in both conversion therapy of non-metastatic unresectable CRC and metastatic CRC.



*Notes: 1. FOLFOX=oxaliplatin + leucovorin + 5-FU; **FOLFIRI**=**irinotecan** + leucovorin+ 5-FU; CapeOx=oxaliplatin + capecitabine.*

Source: CSCO 2023, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on CCA Approved by NMPA

Drug Name	Brand Name	Target	Company	Indication	Approval Date
Durvalumab	英飞凡 IMFINZI	PD-L1	AstraZeneca	CCA	2019-12-06
Pembrolizumab	可瑞达 Keytruda	PD-1	Merck Sharp & Dohme	CCA	2018-07-20

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on CCA Approved by FDA

Drug Name	Brand Name	Target	Company	Indications	Approval Date
DURVALUMAB	IMFINZI	PD-L1	AstraZeneca	CCA	2017-05-01
PEMBROLIZUMAB	KEYTRUDA	PD-1	Merck Sharp & Dohme	CCA	2014-09-04

Note: Approval date: First approval date
As of Mya 9th 2025

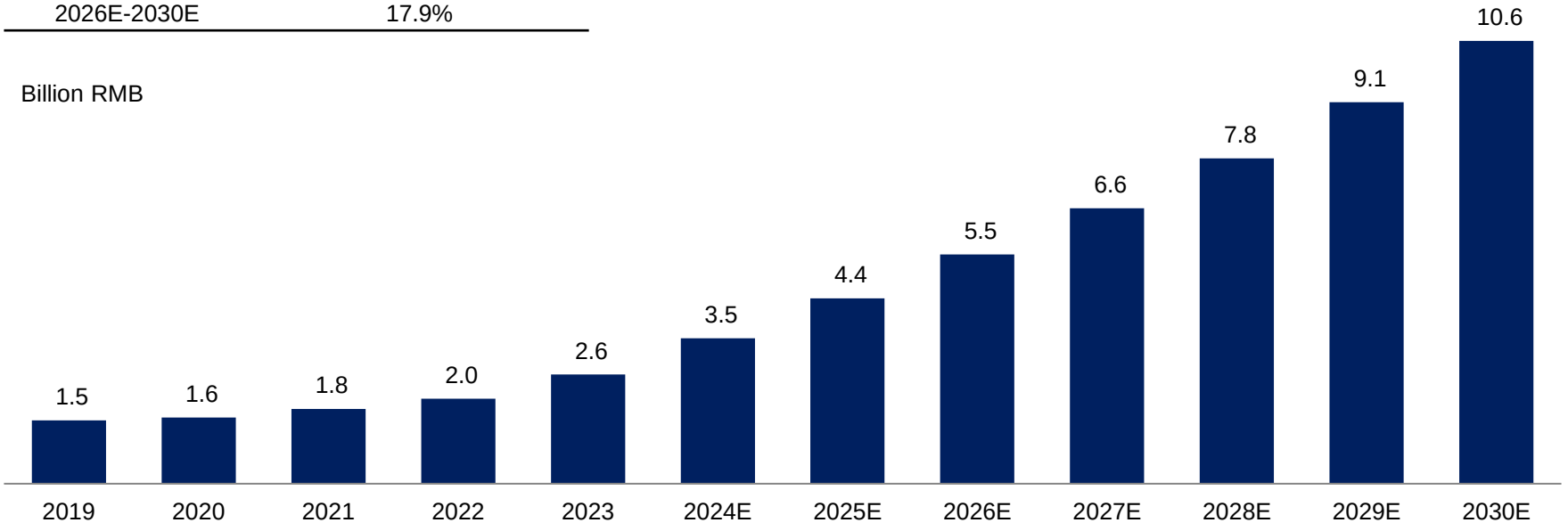
Source: FDA, Frost & Sullivan Analysis

Historical and Forecasted of China CCA Drug Market Size, 2019-2030E

- China's CCA drug market size reached RMB 2.6billion in 2023, with a CAGR of 14.6% from 2019 to 2023. The market size will climb to RMB5.5 billion and RMB10.6 billion in 2026 and 2030 respectively.

Historical and Forecasted of China CCA Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	14.6%
2023-2026E	28.0%
2026E-2030E	17.9%



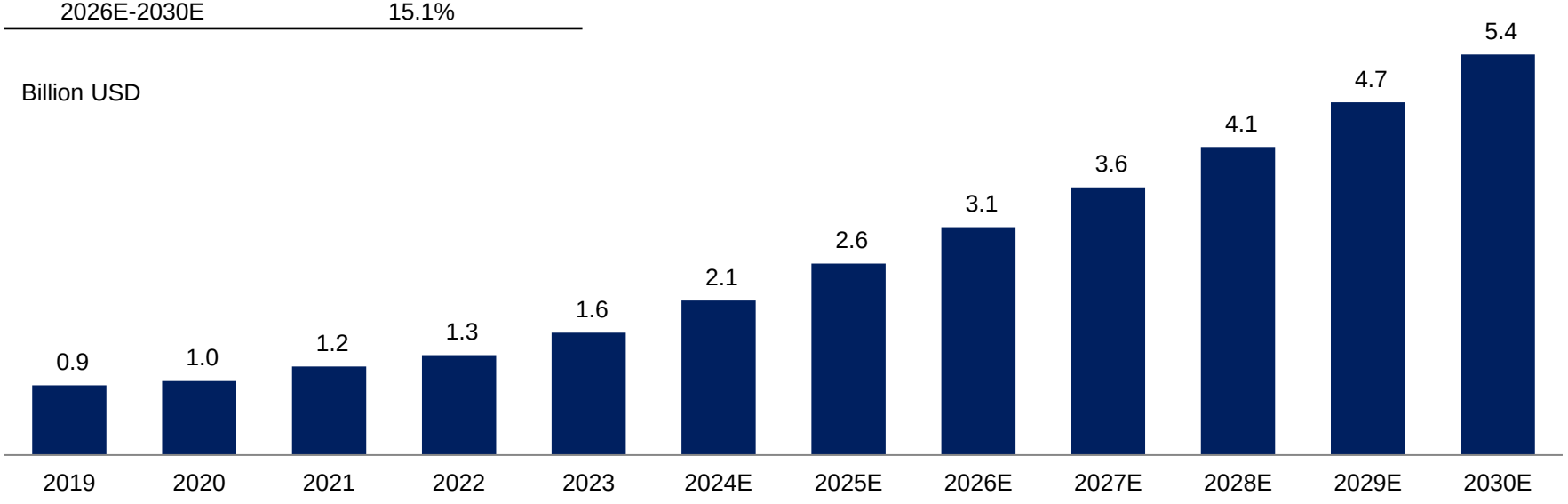
Source: Frost & Sullivan Analysis

Historical and Forecasted of Global CCA Drug Market Size, 2019-2030E

- The global CCA drug market size reached USD1.6 billion in 2023, with a CAGR of 15.1% from 2019 to 2023. The market size is expected to reach USD3.1 billion in 2026, with a CAGR of 23.0% from 2023 to 2026. The market will further grow to USD5.4 billion in 2030, with a CAGR of 15.1% from 2026 to 2030.

Historical and Forecasted of Global CCA Drug Market Size, 2019-2030E

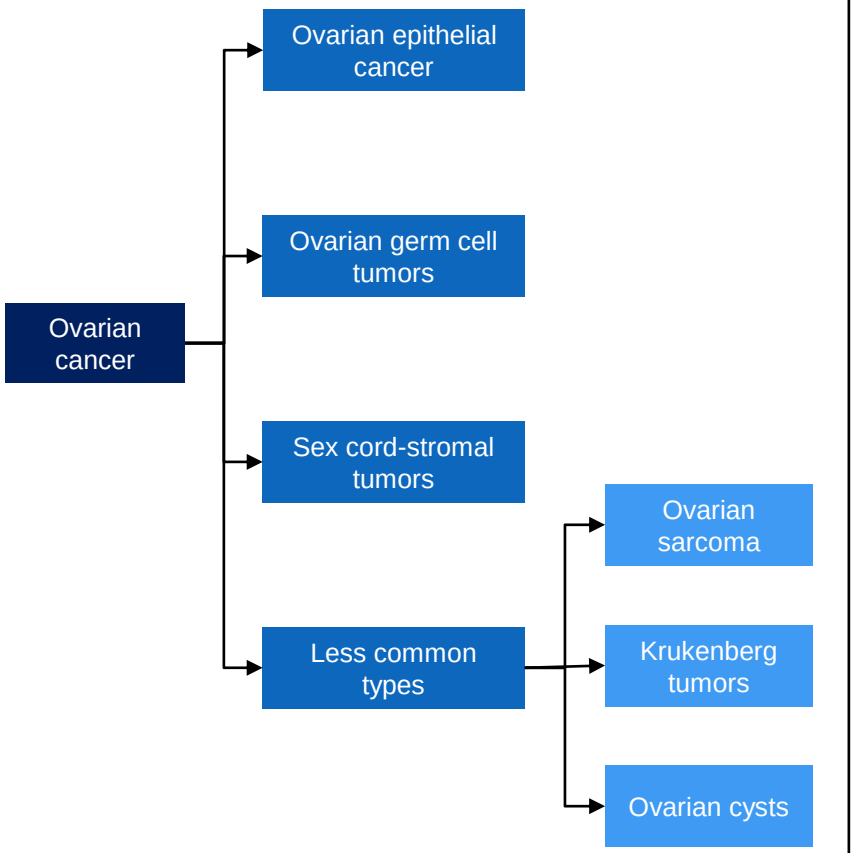
Period	CAGR
2019-2023	15.1%
2023-2026E	23.0%
2026E-2030E	15.1%



Source: Frost & Sullivan Analysis

Overview of Ovarian Cancer

Pathological subtypes of ovarian cancer



Overview

1 Brief Introduction

- Ovarian cancer develops in the ovaries, which are the female reproductive glands that produce eggs during a woman's reproductive years. Ovarian cancer develops when cells in the ovaries begin to grow out of control.
- Ovarian cancer is usually diagnosed at a late stage, contributing to a high recurrence rate and poor prognosis, often leading to death.

2 Symptom

- Early warning signs: Abdominal bloating, indigestion or nausea, changes in appetite, pressure in the pelvis or lower back, a more frequent or urgent need to urinate and/or constipation, changes in bowel movements, increased abdominal girth, tiredness or low energy, changes in menstruation.
- Advanced: Ovarian cysts, masses or tumors

3 Diagnosis

- CT scan, MRI, PET/CT scan, Ultrasound (Imaging tests)
- Advanced genomic testing, nutrition panel, CA-125 test(lab tests); Pelvic exam

4 Risk Factors

- Age (55&above); Family history
- Genetic mutations (BRCA1&BRCA2)
- Lynch syndrome and Peutz-Jeghers syndrome
- Breast, colorectal or endometrial cancer

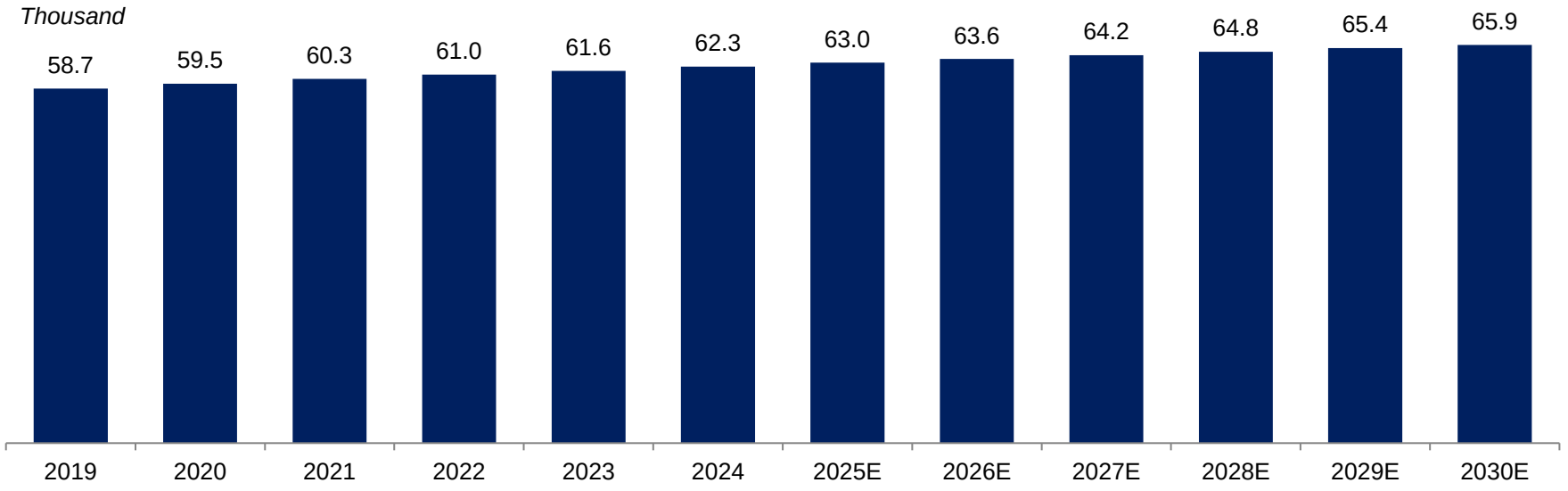
Source: Literature Review, Frost & Sullivan Analysis

Incidence of Ovarian Cancer in China, 2019-2030E

- In China, the number of new incidence cases of ovarian cancer reached 62.3 thousand in 2024, showing a CAGR of 1.2% from 2019. Projections indicate that this figure is expected to rise to 64.2 thousand by 2027, with a CAGR of 1.1% from 2024. It is anticipated that by 2030, the incidence of ovarian cancer will reach 65.9 thousand, representing a CAGR of 0.9% from 2027 to 2030.

Incidence of Ovarian Cancer in China, 2019-2030E

Period	CAGR
2019-2024	1.2%
2024-2027E	1.0%
2027E-2030E	0.9%



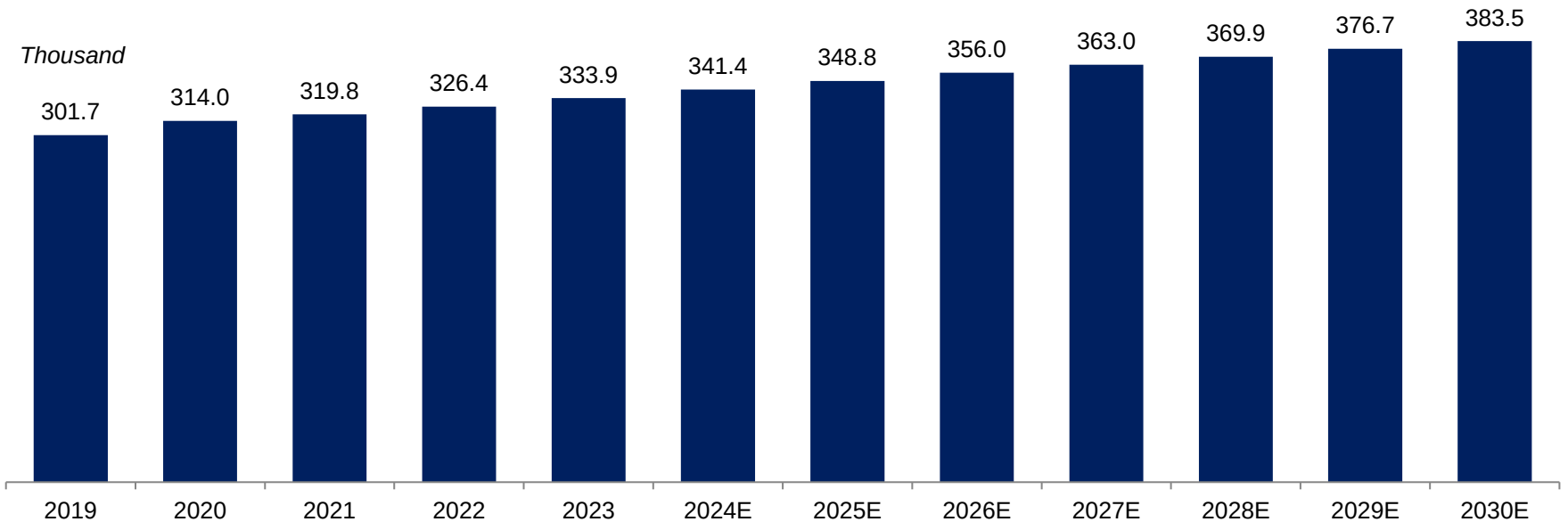
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Ovarian Cancer, 2019-2030E

- Between 2019 and 2023, there was an increase in the global incidence of ovarian cancer from 301.7 thousand to 333.9 thousand, representing a CAGR of 2.6%. It is projected that this number will continue to rise to 356.0 thousand by 2026, at a CAGR of 2.2% from 2023 to 2026. By 2030, it is expected to reach 383.5 thousand, growing at a CAGR of 1.9%.

Global Incidence of Ovarian Cancer, 2019-2030E

Period	CAGR
2019-2023	2.6%
2023-2026E	2.2%
2026E-2030E	1.9%

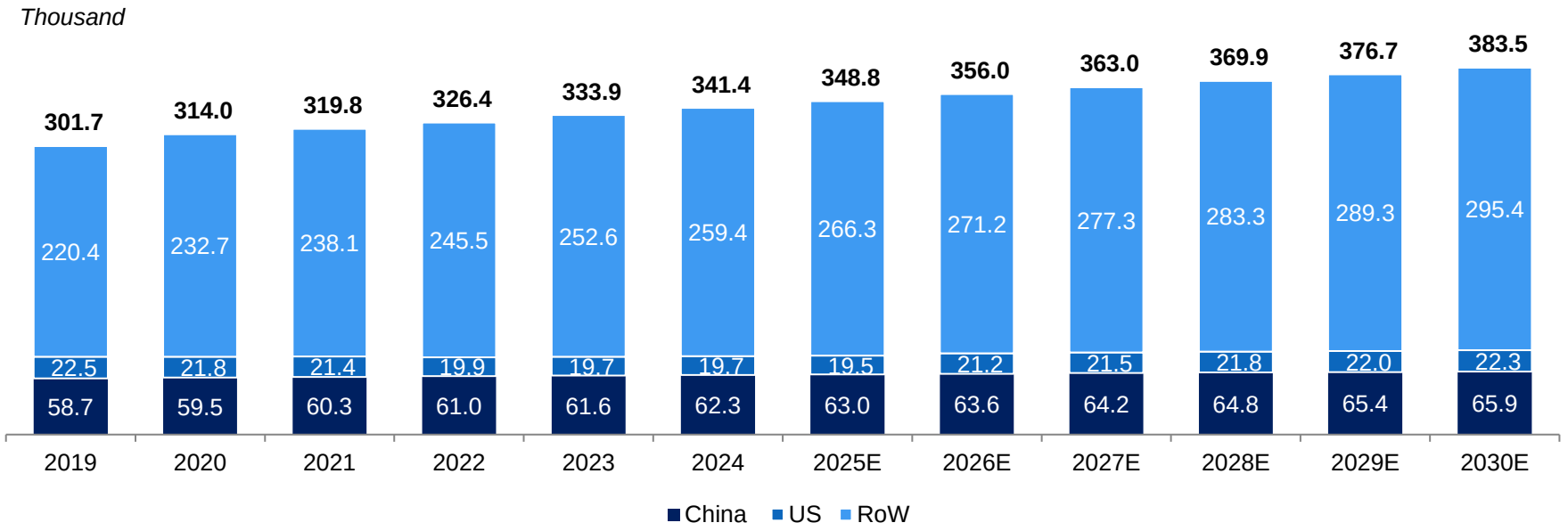


Source: IARC, Frost & Sullivan Analysis

Global Incidence of Ovarian Cancer by Region, 2019-2030E

Global Incidence of Ovarian Cancer by Region, 2019-2030E

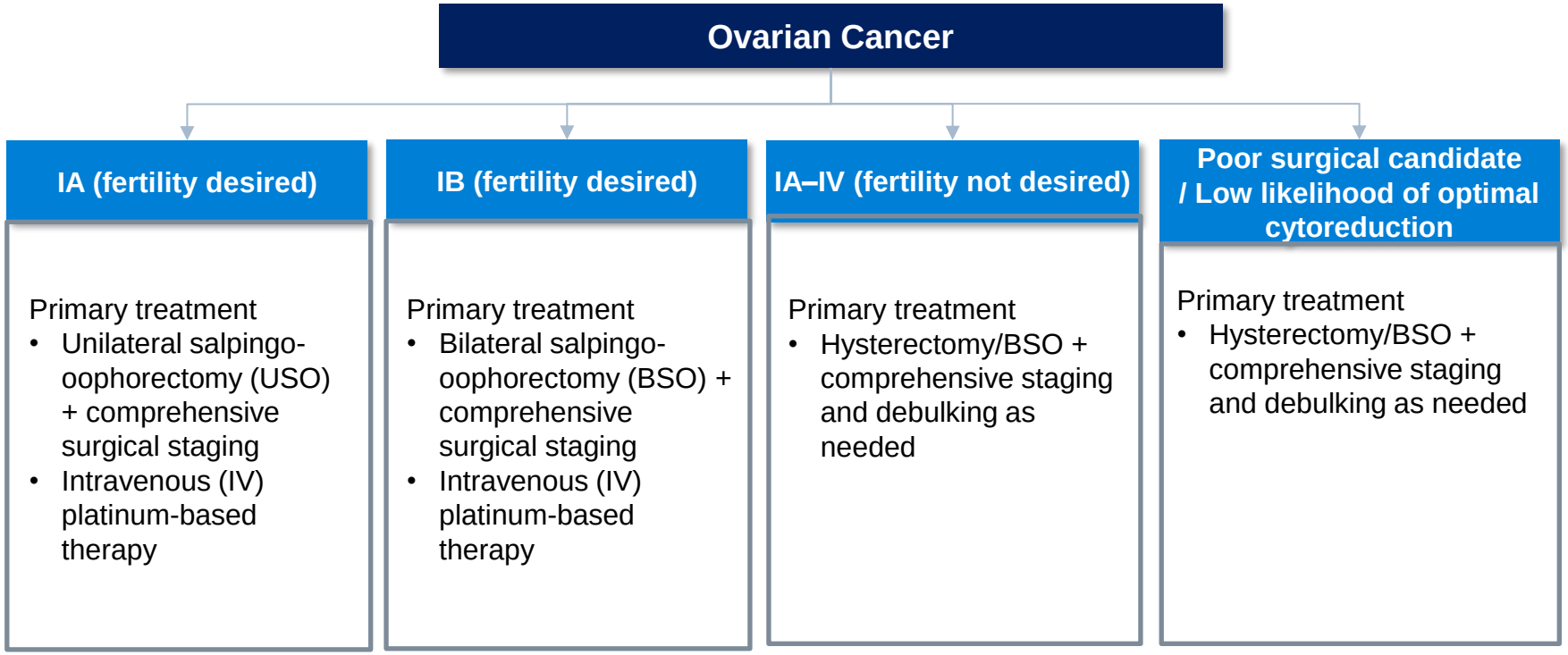
Period	CAGR			
	China	US	RoW	Total
2019-2024	1.2%	-2.7%	3.3%	2.5%
2024-2030E	0.9%	2.1%	2.2%	2.0%



Source: IARC, Frost & Sullivan Analysis

Treatment Paradigm of Ovarian Cancer in the US

- Primary treatment for presumed ovarian, fallopian tube, or primary peritoneal cancer usually consists of appropriate surgical staging and debulking surgery, followed in most (but not all) patients by systemic chemotherapy.



Source: NCCN2024, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Ovarian Cancer Approved by NMPA

Drug Name	Brand Name	Target	Company	Indication	Approval Date
Mirvetuximab	爱拉赫	FRα	AbbVie Inc.	Ovarian Cancer	2024-11-22
Bevacizumab	安维汀 Avastin	VEGF	Roche	Ovarian Cancer	2010-02-26

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Ovarian Cancer Approved by FDA

Drug Name	Brand Name	Target	Company	Indications	Approval Date
BEVACIZUMAB	AVASTIN	VEGF	ROCHE	Ovarian Cancer	2004-02-26

Note: Approval date: First approval date
As of Mya 9th 2025

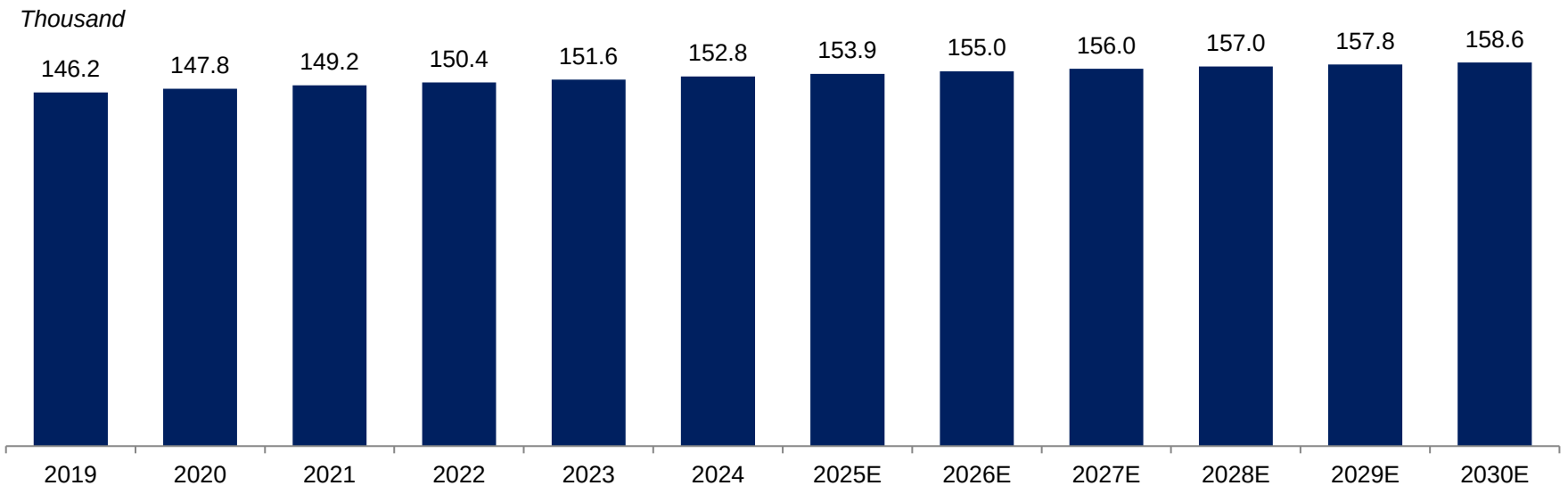
Source: FDA, Frost & Sullivan Analysis

Incidence of Cervical Cancer in China, 2019-2030E

- In China, the number of new incidence cases of cervical cancer reached 152.8 thousand in 2024, showing a CAGR of 0.9% from 2019. Projections indicate that this figure is expected to rise to 156.0 thousand by 2027, with a CAGR of 0.7% from 2024. It is anticipated that by 2030, the incidence of cervical cancer will reach 158.6 thousand, representing a CAGR of 0.6% from 2027 to 2030.

Incidence of Cervical Cancer in China, 2019-2030E

Period	CAGR
2019-2024	0.9%
2024-2027E	0.7%
2027E-2030E	0.6%



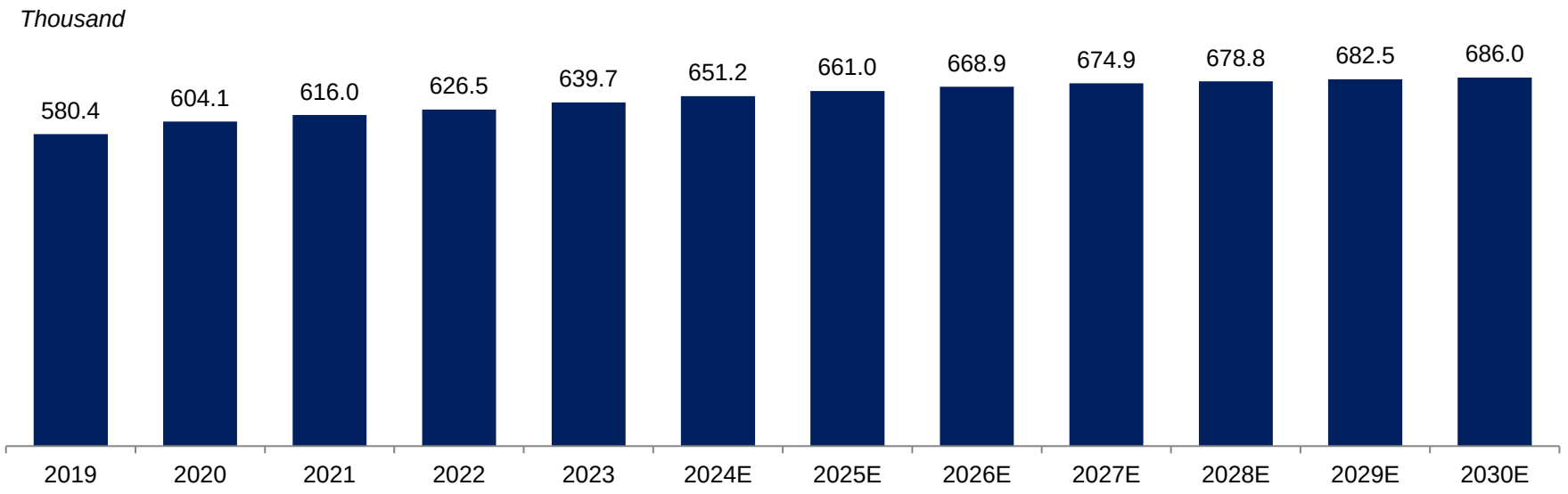
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Cervical Cancer, 2019-2030E

- Between 2019 and 2023, there was an increase in the global incidence of cervical cancer from 580.4 thousand to 639.7 thousand, representing a CAGR of 2.5%. It is projected that this number will continue to rise to 668.9 thousand by 2026, at a CAGR of 1.5% from 2023 to 2026. By 2030, it is expected to reach 686.0 thousand, growing at a CAGR of 0.6%.

Global Incidence of Cervical Cancer, 2019-2030E

Period	CAGR
2019-2023	2.5%
2023-2026E	1.5%
2026E-2030E	0.6%



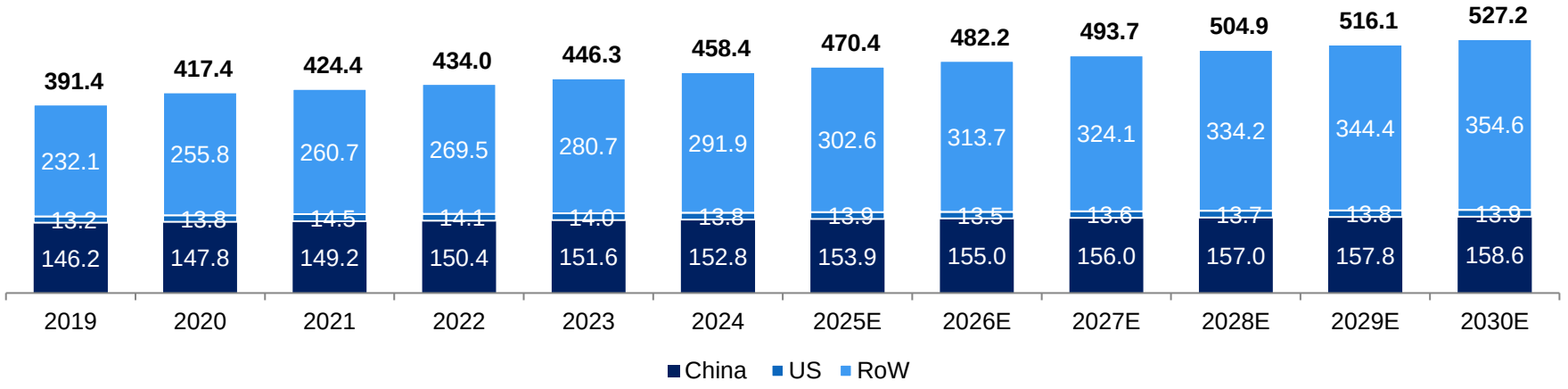
Source: IARC, Frost & Sullivan Analysis

Global Incidence of Cervical Cancer by Region, 2019-2030E

Global Incidence of Cervical Cancer by Region, 2019-2030E

Period	CAGR			
	China	US	RoW	Total
2019-2024	0.9%	1.0%	4.7%	3.2%
2024-2030E	0.6%	-0.2%	3.3%	2.4%

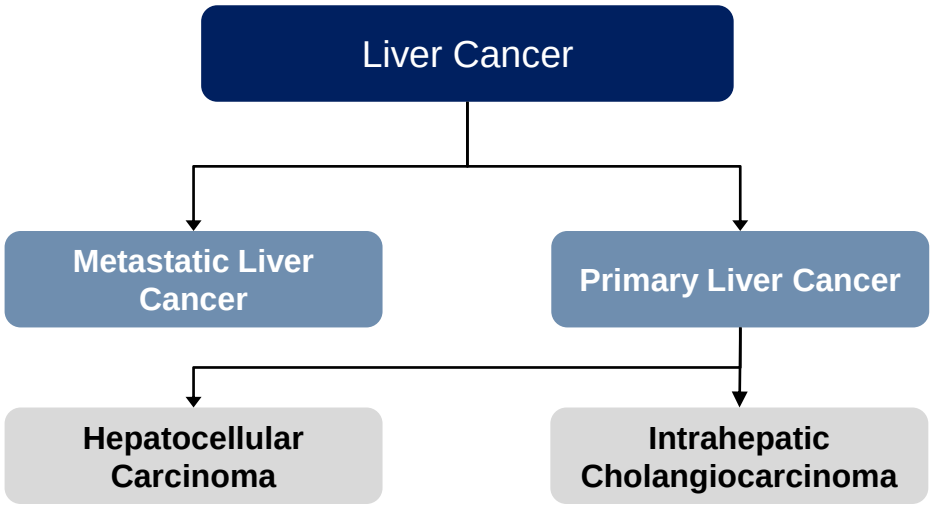
Thousand



Source: IARC, Frost & Sullivan Analysis

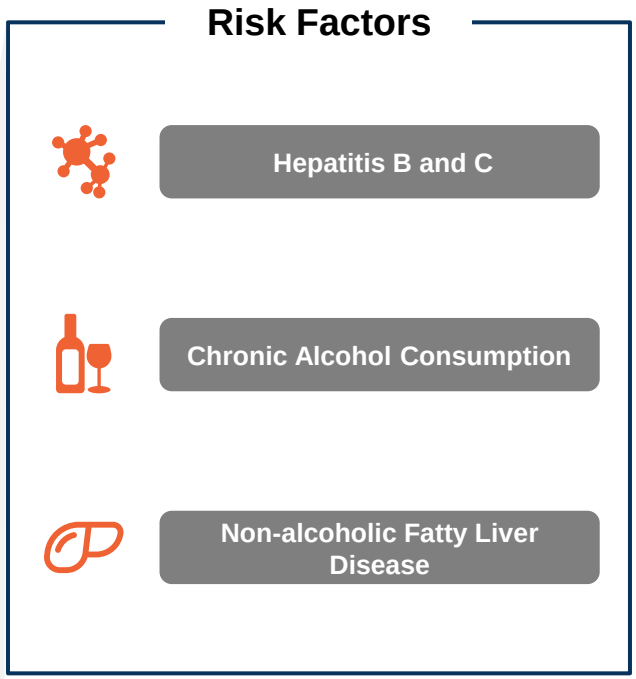
Overview of Liver Cancer

- Liver Cancer is the growth and spread of unhealthy cells in the liver. Hepatocellular carcinoma (HCC) is the most common type of primary liver cancer (~90%), and is the most common cause of death in people with cirrhosis.
- The major symptoms of HCC include yellow skin, abdominal swelling due to fluid in the abdominal cavity, easy bruising from blood clotting abnormalities, loss of appetite, unintentional weight loss, abdominal pain, nausea, vomiting, etc.



- The most common type of primary liver cancer in adults.
- HCC occurs most often in people with chronic liver diseases, such as cirrhosis caused by hepatitis B or hepatitis C infection.

- Bile duct cancer is the second most common malignancy arising from the liver.
- It develops in the smaller bile duct branches inside the liver.



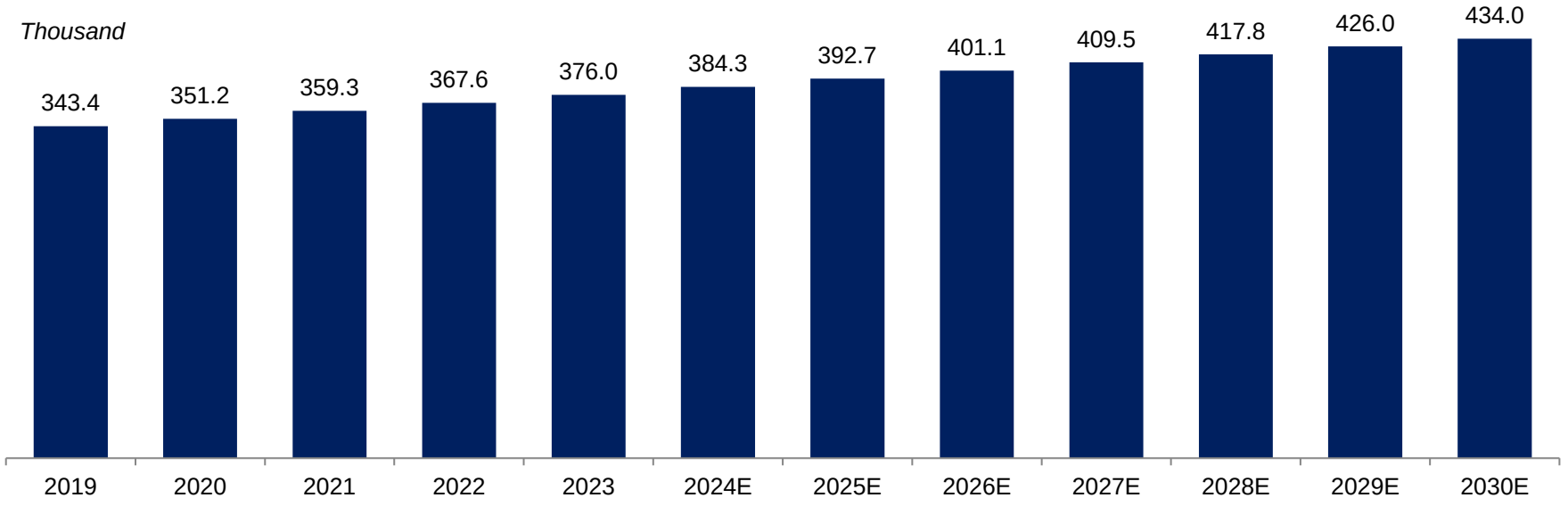
Source: Frost & Sullivan Analysis

Incidence of Liver Cancer in China, 2019-2030E

- In China, new case of liver cancer reached 376.0 thousand in 2023 at a CAGR of 2.3% from 2019. It is projected to further increase to 401.1 thousand in 2026, representing a CAGR of 2.2% from 2023. It is estimated that the incidence would achieve 434.0 thousand in 2030, representing a CAGR of 2.0% from 2026 to 2030.

Incidence of Liver Cancer in China, 2019-2030E

Period	CAGR
2019-2023	2.3%
2023-2026E	2.2%
2026E-2030E	2.0%



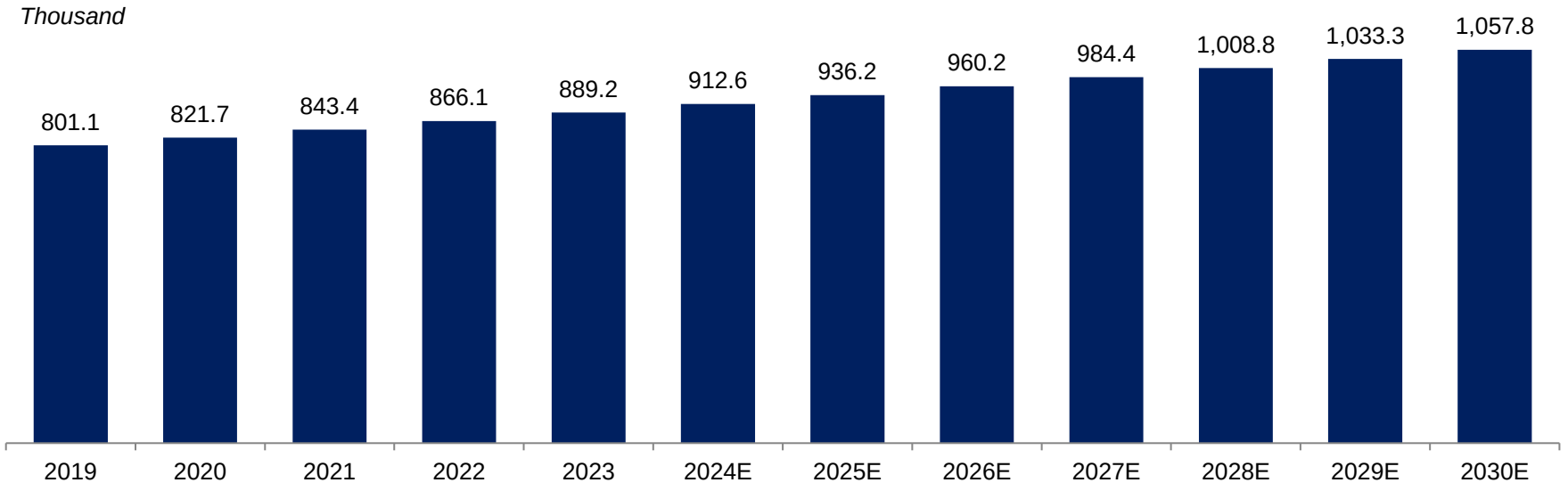
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Liver Cancer, 2019-2030E

- Between 2019 and 2023, there was an increase in the global incidence of liver cancer from 801.1 thousand to 889.2 thousand, representing a CAGR of 2.6%. It is projected that this number will continue to rise to 960.2 thousand by 2026, at a CAGR of 2.6% from 2023 to 2026. By 2030, it is expected to reach 1,057.8 thousand, growing at a CAGR of 2.4%.

Global Incidence of Liver Cancer, 2019-2030E

Period	CAGR
2019-2023	2.6%
2023-2026E	2.6%
2026E-2030E	2.4%



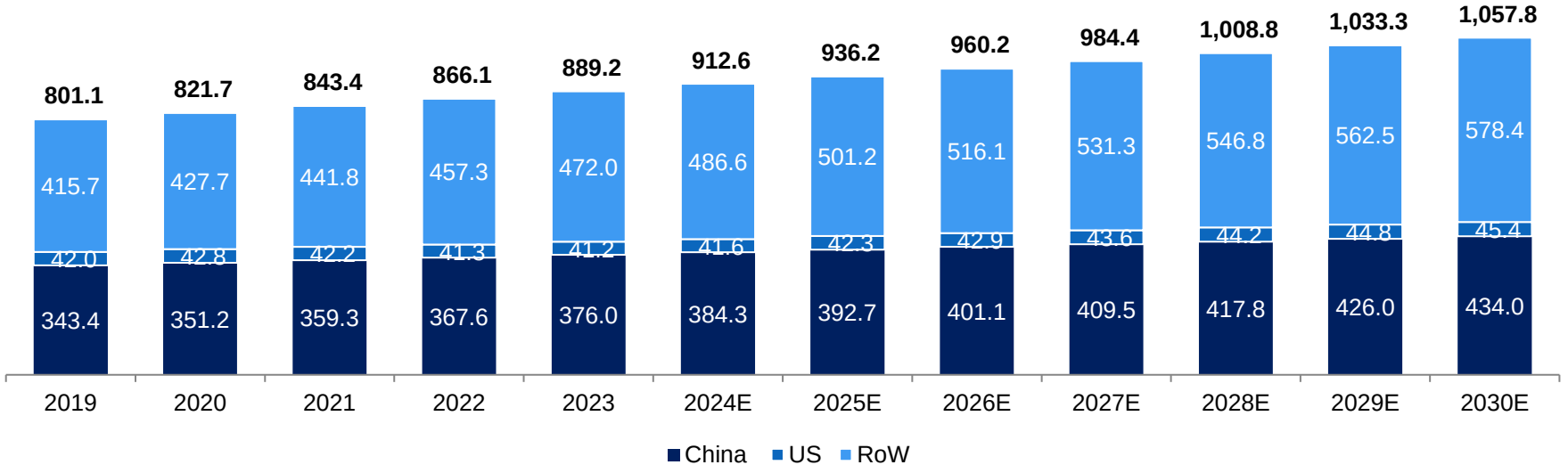
Source: IARC, Frost & Sullivan Analysis

Global Incidence of Liver Cancer by Region, 2019-2030E

Global Incidence of Liver Cancer by Region, 2019-2030E

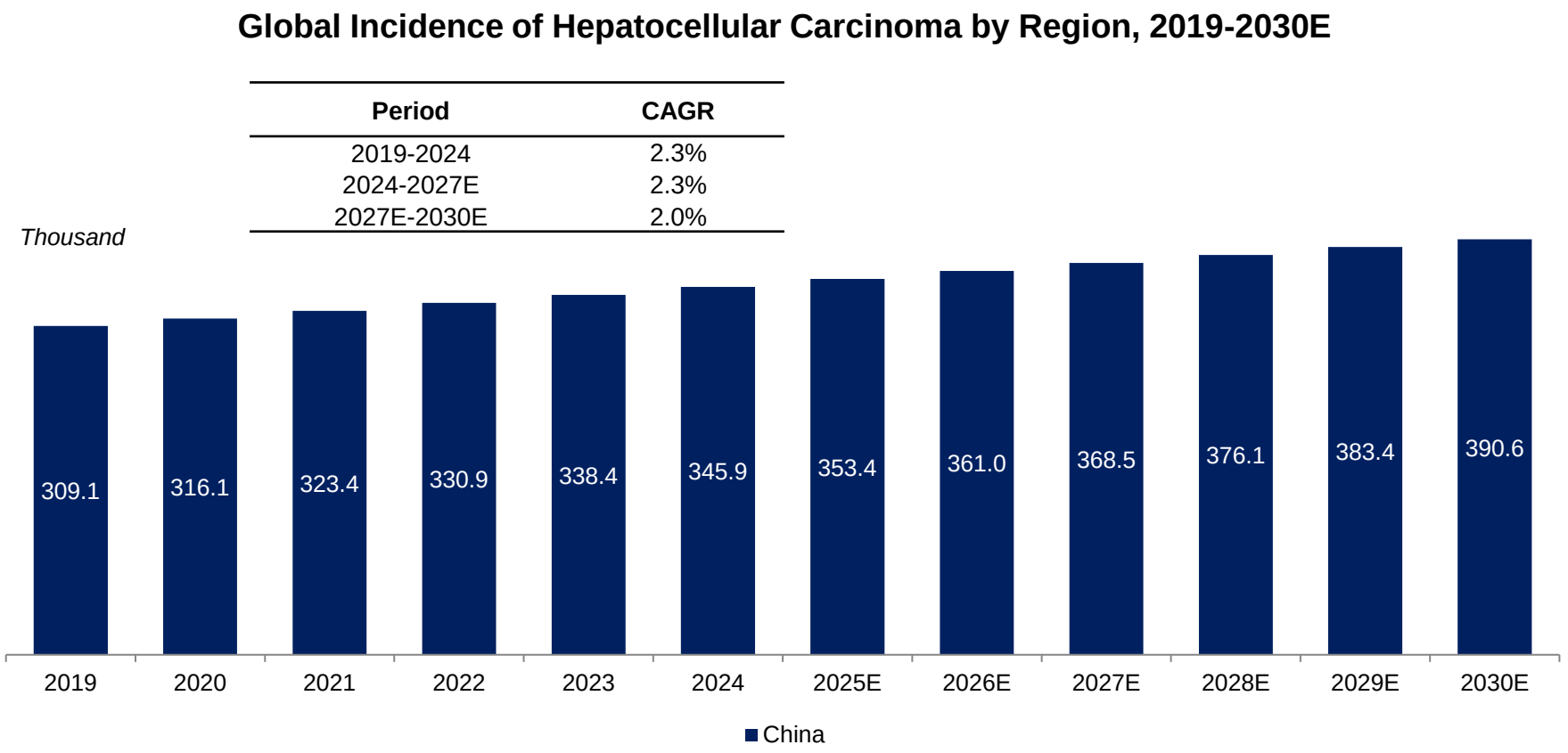
Period	CAGR			
	China	US	RoW	Total
2019-2023	2.3%	-0.5%	3.2%	2.6%
2023-2026E	2.2%	1.4%	3.0%	2.6%
2026E-2030E	2.0%	1.4%	2.9%	2.4%

Thousand



Source: IARC, Frost & Sullivan Analysis

Global Incidence of Hepatocellular Carcinoma by Region, 2019-2030E



Source: IARC, Frost & Sullivan Analysis

Treatment Paradigm of HCC in China

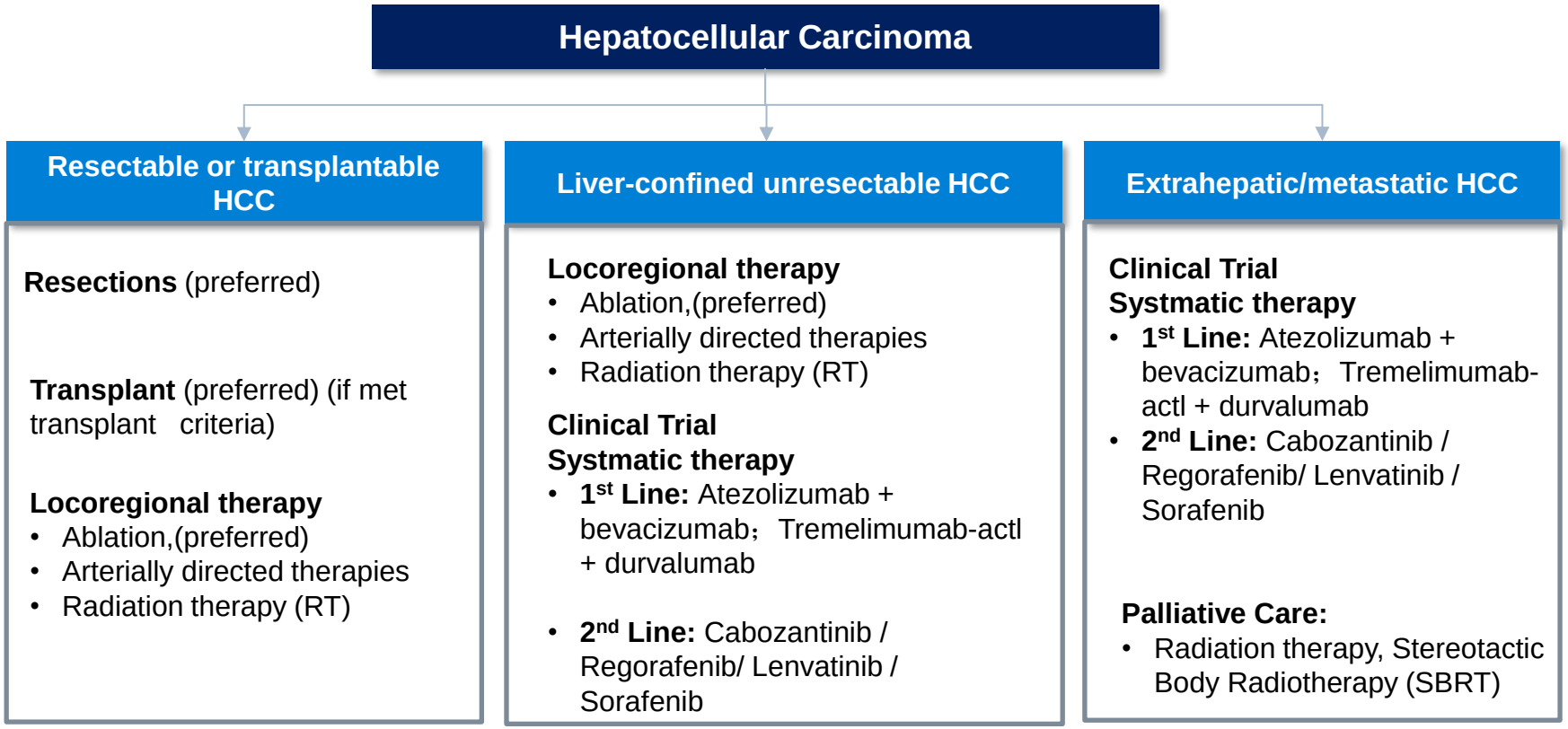
- According to CSCO Guidelines, HCC treatment options are different depend on the stage of the disease. For early stage HCC patients, locoregional therapies are mostly adopted while for late stage patients, the recommended treatment options are majorly systemic therapies.

Disease Stage	Recommended Therapies	Summary
Early Stage	**Liver Resection**; **Tumor Ablation**; **Radiation Therapy**; **Radio-immuno-therapy**; **Liver Transplant-ation** + TACE; Immuno-modulators; Chemotherapy; Targeted Therapy (e.g. sorafenib)	Early stage HCC treatment options are majorly locoregional ones such as liver resection, ablation, radiation therapy, radioimmunotherapy, which can be used in combination with TACE, immunomodulators, chemotherapy or targeted therapies to achieve a better treatment outcome.
Late Stage	**Small molecule targeted therapy**: **1st Line:** Sorafenib, Lenvatinib, Donafenib; Sintilimab + Bevacizumab Apatinib + Camrelizumab, Immobilizumab + temselimumab, akradine; **2nd Line:** Regorafenib, Apatinib) **Checkpoint inhibitors + (Monoclonal antibody)** (**1st Line:** Atelizumab + Bevacivumab; **2nd Line**: PD-1) **Chemotherapy** (Oxaliplatin-based, etc)	Late stage HCC treatment options are majorly systemic treatments, including small molecular targeted therapy, checkpoint inhibitor alone or with anti-angiogenic monoclonal antibodies (such as bevacivumab) as well as chemotherapy.

Source: CSCO 2022, Frost & Sullivan Analysis

Treatment Paradigm of HCC in the U.S.

- All patients with hepatocellular carcinoma (HCC) should be evaluated for potential curative treatments, including surgical resection, liver transplantation, and ablative strategies for smaller lesions.
- Locoregional therapy for HCC includes ablation techniques like microwave or radiofrequency ablation, effective for small tumors up to 3 cm, and arterially directed therapies such as TAE and TACE targeting the tumor's arterial supply. Radiotherapy is used for inaccessible tumors or when other treatments are unsuitable due to patient health conditions.



Source: NCCN 2024, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Liver Cancer Approved by NMPA

Drug Name	Brand Name	Target	Company	Indication	Approval Date
Nivolumab	欧狄沃 OPDIVO	PD-1	Bristol Myers Squibb	Liver Cancer	2025-04-22
Ramucirumab	希冉择 Cyramza	VEGFR2	Eli Lilly	Liver Cancer	2022-03-16
Atezolizumab	泰圣奇 Tecentriq	PD-L1	Roche	Liver Cancer	2020-02-11
Tislelizumab	百泽安	PD-1	Boehringer Ingelheim / BeiGene	Liver Cancer	2019-12-26
Camrelizumab	艾瑞卡	PD-1	Hengrui Medicine Co,.Ltd.	Liver Cancer	2019-05-29
Sintilimab	达伯舒	PD-1	Innovent Biologics Co., Ltd.	Liver Cancer	2018-12-24
Pembrolizumab	可瑞达 Keytruda	PD-1	Merck Sharp & Dohme	Liver Cancer	2018-07-20
Bevacizumab	安维汀 Avastin	VEGF	Roche	Liver Cancer	2010-02-26

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Liver Cancer Approved by FDA

Drug Name	Brand Name	Target	Company	Indications	Approval Date
TREMELIMUMAB-ACTL	IMJUDO	CTLA4	ASTRAZENECA	Liver Cancer	2022-10-21
ATEZOLIZUMAB	TECENTRIQ	PD-L1	GENENTECH INC	Liver Cancer	2016-05-18
NIVOLUMAB	OPDIVO	PD-1	BRISTOL MYERS SQUIBB	Liver Cancer	2014-12-22
PEMBROLIZUMAB	KEYTRUDA	PD-1	MERCK SHARP DOHME	Liver Cancer	2014-09-04
RAMUCIRUMAB	CYRAMZA	VEGFR2	ELI LILLY AND CO	Liver Cancer	2014-04-21
IPILIMUMAB	YERVOY	CTLA4	BRISTOL MYERS SQUIBB	Liver Cancer	2011-03-25
BEVACIZUMAB	AVASTIN	VEGF	ROCHE	Liver Cancer	2004-02-26

Note: Approval date: First approval date
As of Mya 9th 2025

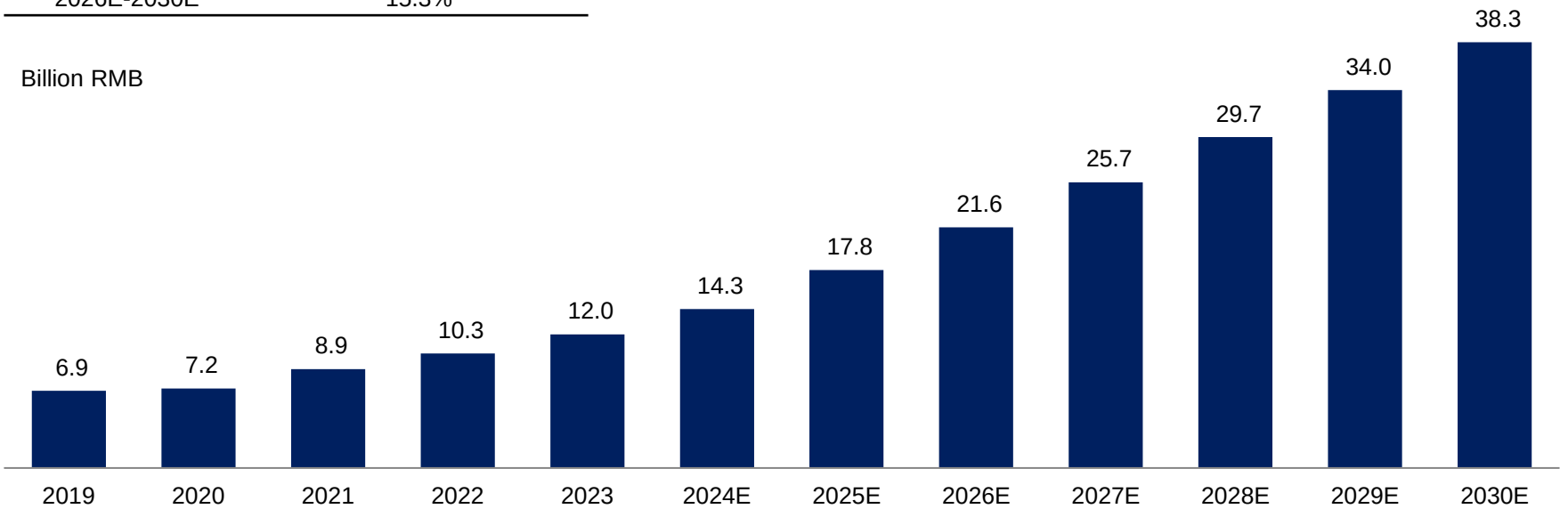
Source: FDA, Frost & Sullivan Analysis

Historical and Forecasted of China HCC Drug Market Size, 2019-2030E

- China's HCC drug market size reached RMB12.0 billion in 2023, with a CAGR of 14.7% from 2019 to 2023. The market size will climb to RMB21.6 billion and RMB38.3 billion in 2026 and 2030 respectively.

Historical and Forecasted of China HCC Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	14.7%
2023-2026E	21.7%
2026E-2030E	15.3%



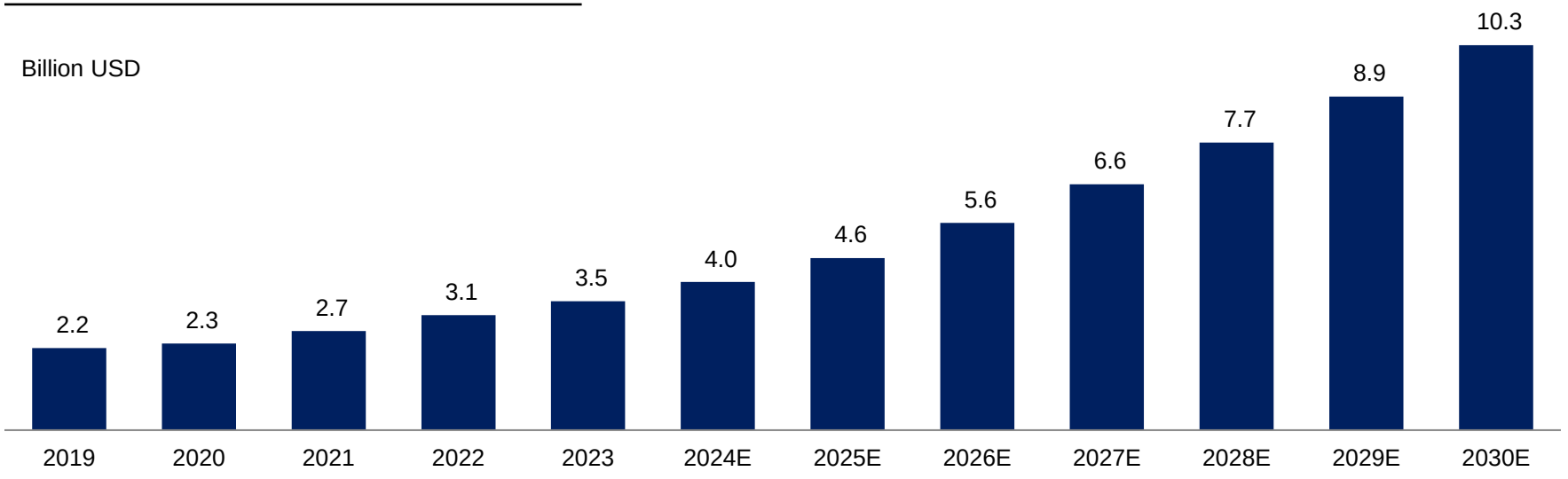
Source: Frost & Sullivan Analysis

Historical and Forecasted of Global HCC Drug Market Size, 2019-2030E

- The global HCC drug market size reached USD3.5 billion in 2023, with a CAGR of 11.9% from 2019 to 2023. The market size is expected to reach USD5.6 billion in 2026, with a CAGR of 21.7% from 2023 to 2026. The market will further grow to USD10.3 billion in 2030, with a CAGR of 16.7% from 2026 to 2030.

Historical and Forecasted of Global HCC Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	11.9%
2023-2026E	17.2%
2026E-2030E	16.7%



Source: Frost & Sullivan Analysis

Overview of Nasopharyngeal Cancer

- Nasopharyngeal cancer is a type of head and neck cancer mostly common in epithelia cells lining the inner surface of the nasopharynx. Nasopharynx is located at the upper part of the pharynx that lies behind the nasal cavity. Due to this central location and its innocuous, subtle symptoms, early diagnosis of nasopharyngeal carcinoma is difficult.
- Early stage of NPC is asymptomatic. The presenting symptom which prompts most people to seek doctors is a lump and mass in the neck, following by nasal blockage, nasal bleeding, and aural impairment. Other symptoms may include trouble breathing, talking, or facial pain and numbness.

Nasopharyngeal Carcinoma

Non-Keratinizing Squamous cell Carcinoma	Keratinizing Squamous Carcinoma	Basaloid Squamous Cell Carcinoma (BSCC)
An aggressive cancer that tends to spread quickly to surrounding tissues and lymph nodes and accounted for most of nasopharyngeal carcinoma. It is strongly associated with Epstein-Barr virus (EBV).	The mucosa cancer cells in nasopharynx are covered by keratin. It is less common than non-keratinizing squamous cell carcinoma and usually develop among individuals over 40 with a history of drinking alcohol.	BSCC is one of the rarest and most aggressive variants of squamous cell carcinoma which often associated with heavy smoking and alcohol drinking habit. Few of squamous cell carcinoma are classified as BSCC.

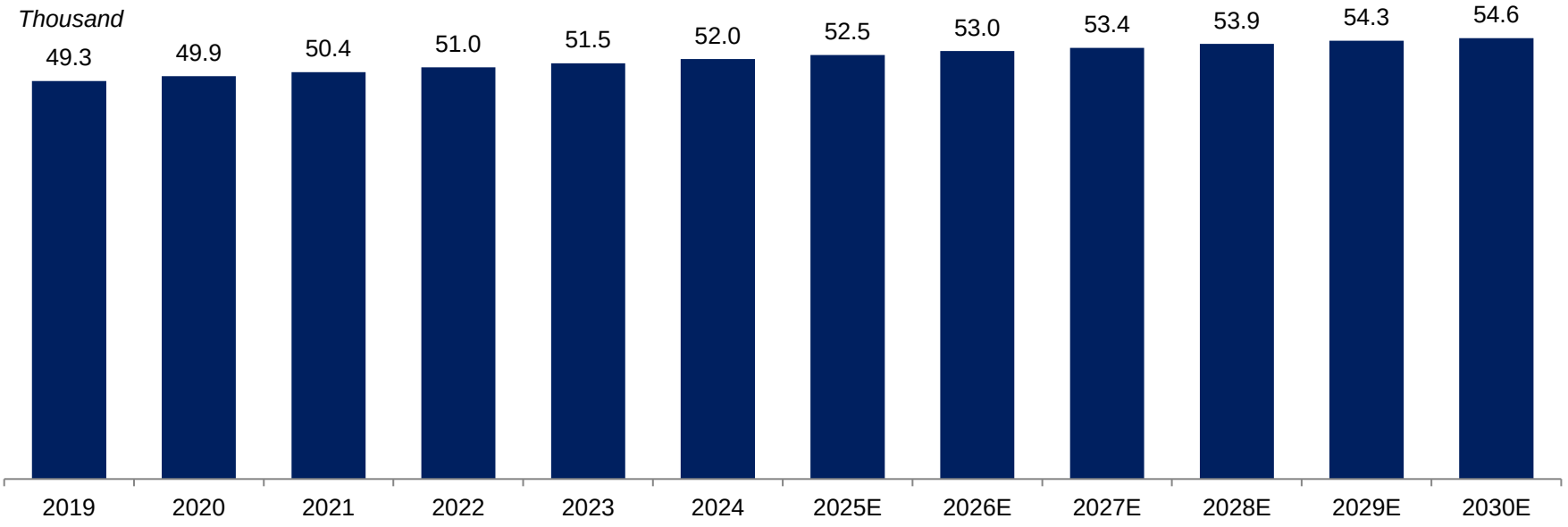
Source: NIH, Frost & Sullivan Analysis

Incidence of Nasopharyngeal Cancer in China, 2019-2030E

- In China, the number of new nasopharyngeal cases rose to 52.0 thousand in 2024, marking a 1.1% CAGR from 2019. Projections indicate a further increase to 53.4 thousand by 2027, with a CAGR of 0.9% from 2024. By 2030, it is anticipated that the incidence will reach 54.6 thousand, reflecting a CAGR of 0.7% from 2027 to 2030.

Incidence of Nasopharyngeal Cancer in China, 2019-2030E

Period	CAGR
2019-2024	1.1%
2024-2027E	0.9%
2027E-2030E	0.7%



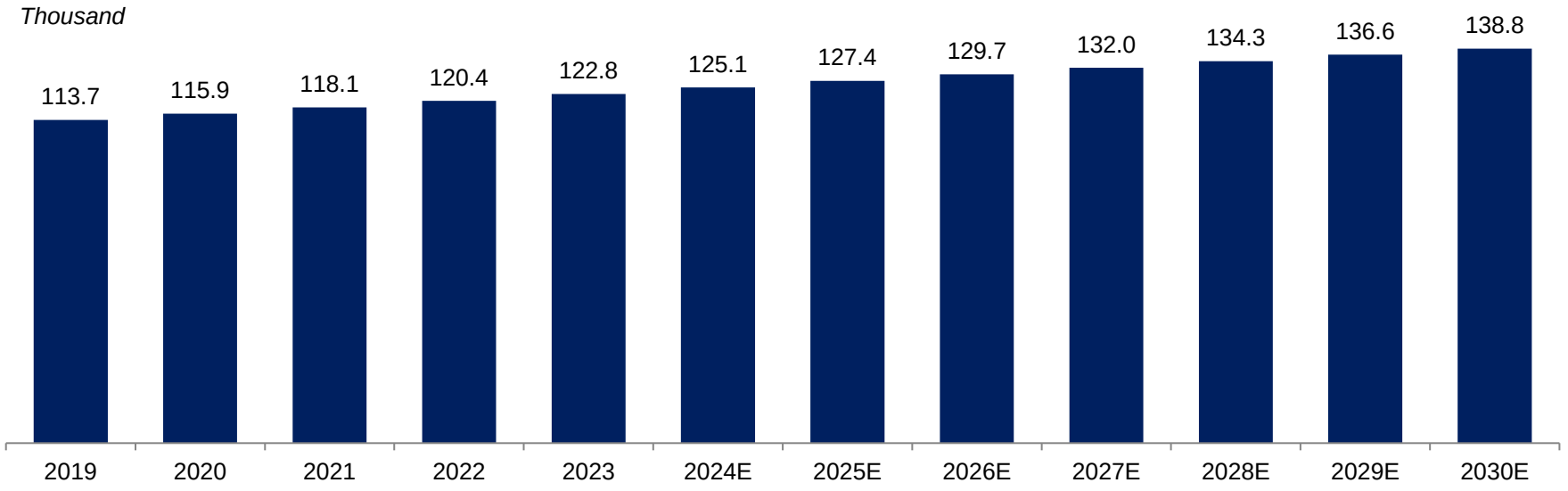
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Nasopharyngeal Cancer, 2019-2030E

- From 2019 to 2023, the worldwide incidence of nasopharyngeal cancer rose from 113.7 thousand to 122.8 thousand, marking a CAGR of 1.9%. Predictions indicate that this figure will further climb to 129.7 thousand by 2026, maintaining the same CAGR of 1.8% from 2023 to 2026. By 2030, it is anticipated to reach 138.8 thousand, at a CAGR of 1.7% annually.

Global Incidence of Nasopharyngeal Cancer, 2019-2030E

Period	CAGR
2019-2023	1.9%
2023-2026E	1.8%
2026E-2030E	1.7%



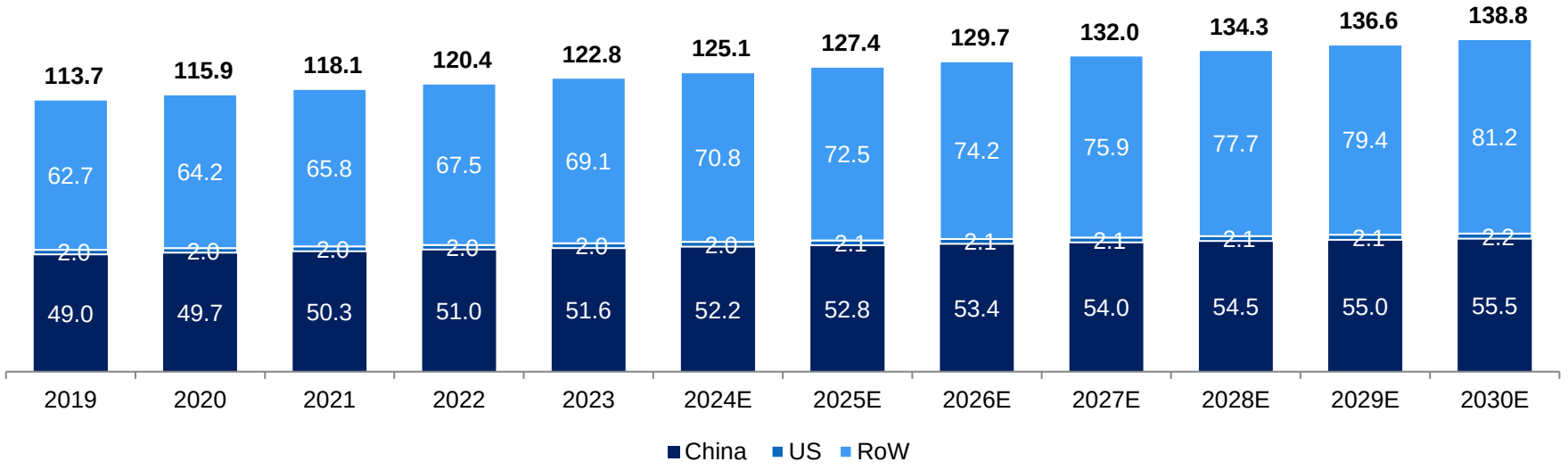
Source: IARC, Frost & Sullivan Analysis

Global Incidence of Nasopharyngeal Cancer by Region, 2019-2030E

Global Incidence of Nasopharyngeal Cancer by Region, 2019-2030E

Period	CAGR			
	China	US	RoW	Total
2019-2024	1.3%	0.9%	2.5%	1.9%
2024-2030E	1.0%	0.9%	2.3%	1.8%

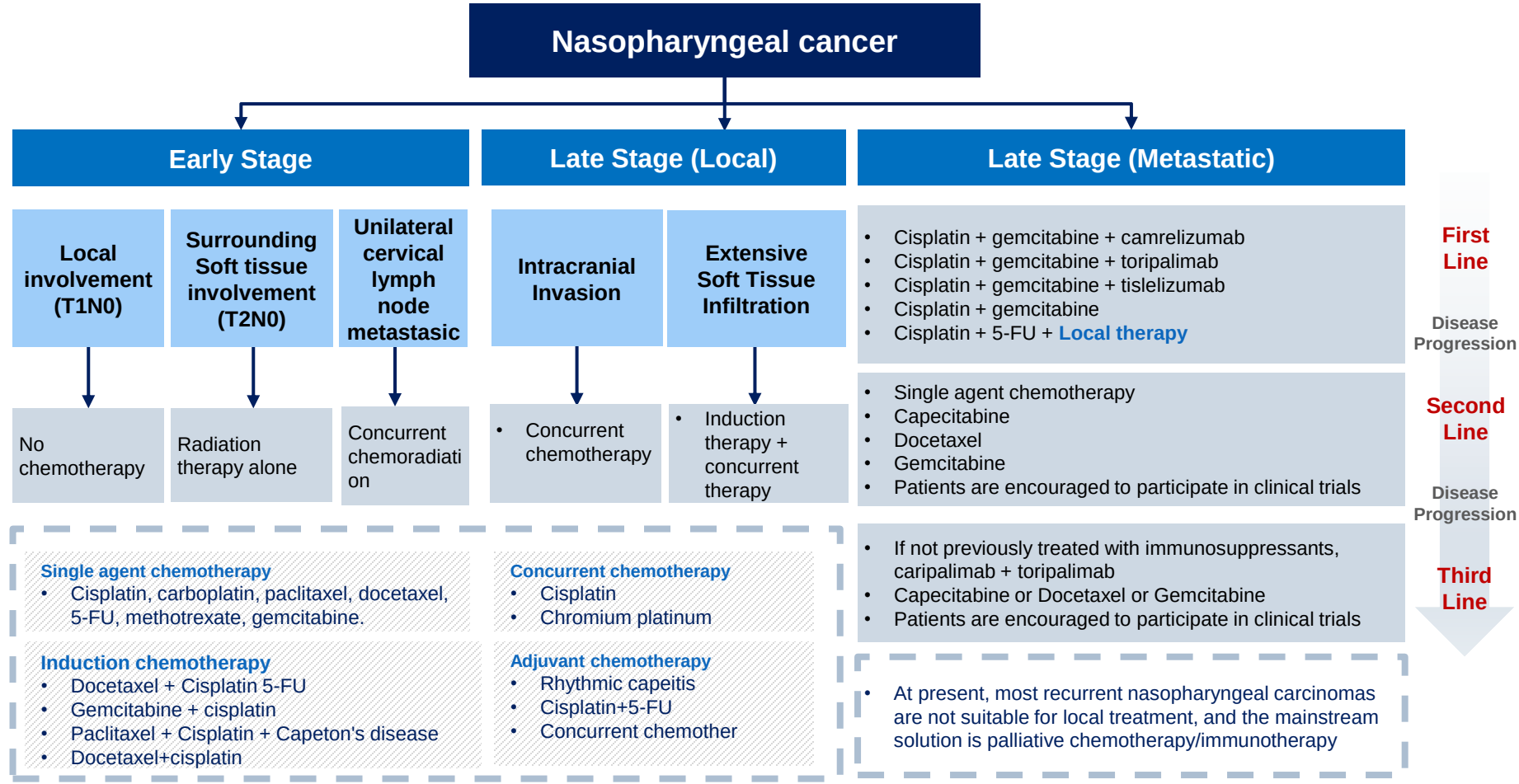
Thousand



Source: IARC, Frost & Sullivan Analysis

Treatment Paradigm of Nasopharyngeal Cancer in China

- The diagnosis and treatment of Nasopharyngeal cancer should attach great importance to the role of the multidisciplinary team, especially for patients with locally advanced and advanced nasopharyngeal cancer.



Source: CSCO 2023, Frost & Sullivan Analysis

Treatment Paradigm of Nasopharyngeal Cancer in U.S.

- The NCCN guidelines provide corresponding guidance for systemic therapy of nasopharyngeal cancer and emphasize that the recommended treatment regimen is based on clinical trial data of EBV-related nasopharyngeal cancer.

Disease Stage	Treatment				
M0	Early Stage (T1-2) →	Definitive Radiotherapy(RT) to nasopharynx Elective Radiotherapy(RT) to neck	± Concurrent systemic therapy	• For patients with early-stage tumors RT alone was recommended because this approach provides excellent locoregional control and avoids the potential toxicity of additional chemotherapy.	
	Advanced Stage (T3-4) →	**Concurrent systemic therapy/ RT:** Platinum-based regimens	**Systemic Therapy/RT Followed by Adjuvant Chemotherapy:** Cisplatin + RT followed by cisplatin/5-FU	**Induction/Systemic Therapy:** • Gemcitabine/cisplatin • Docetaxel/cisplatin/5-FU	**Clinical trials**
M1	**Oligometastatic disease** →	• Induction chemotherapy followed by RT • Cisplatin/RT • Concurrent cisplatin + RT • Systemic therapy			
	Widely metastatic and Good PS →	• Definitive RT to primary and regional nodesn (preferred) and to oligometastases as indicated • Continued systemic therapy			
	Widely metastatic and Poor PS →	• Best Supportive care			

Recurrent, Unresectable (with no sugery or RT option)

First-Line Treatments:
- Cisplatin/gemcitabine
- Cisplatin/gemcitabine with toripalimab-tpzi

Subsequent-Line Therapy:
- Toripalimab-tpzi after disease progression on platinum-containing therapy

Single Agents:
- Cisplatin, carboplatin, paclitaxel, docetaxel, 5-FU, methotrexate, gemcitabine, capecitabine

Source: NCCN 2024, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Nasopharyngeal Carcinoma Approved by NMPA

Drug Name	Brand Name	Target	Company	Indication	Approval Date
Tagitanlimab	科泰莱	PD-1	Sichuan Kelun-Biotech Biopharmaceutical Co.,LTD	Nasopharyngeal Carcinoma	2024-12-25
Penpulimab	安尼可	PD-1	Akeso / Chiatai Tianqing Pharmaceutical Group	Nasopharyngeal Carcinoma	2021-08-03
Tislelizumab	百泽安	PD-1	Boehringer Ingelheim / BeiGene	Nasopharyngeal Carcinoma	2019-12-26
Toripalimab	拓益	PD-1	Junshi Biosciences Co.，Ltd.	Nasopharyngeal Carcinoma	2018-12-17
Camrelizumab	艾瑞卡	PD-1	Hengrui Medicine Co,.Ltd.	Nasopharyngeal Carcinoma	2019-05-29
Nimotuzumab	泰欣生	EGFR	Biotech Pharmaceuticals Co., Ltd.	Nasopharyngeal Carcinoma	2008-01-07

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Nasopharyngeal Carcinoma Approved by FDA

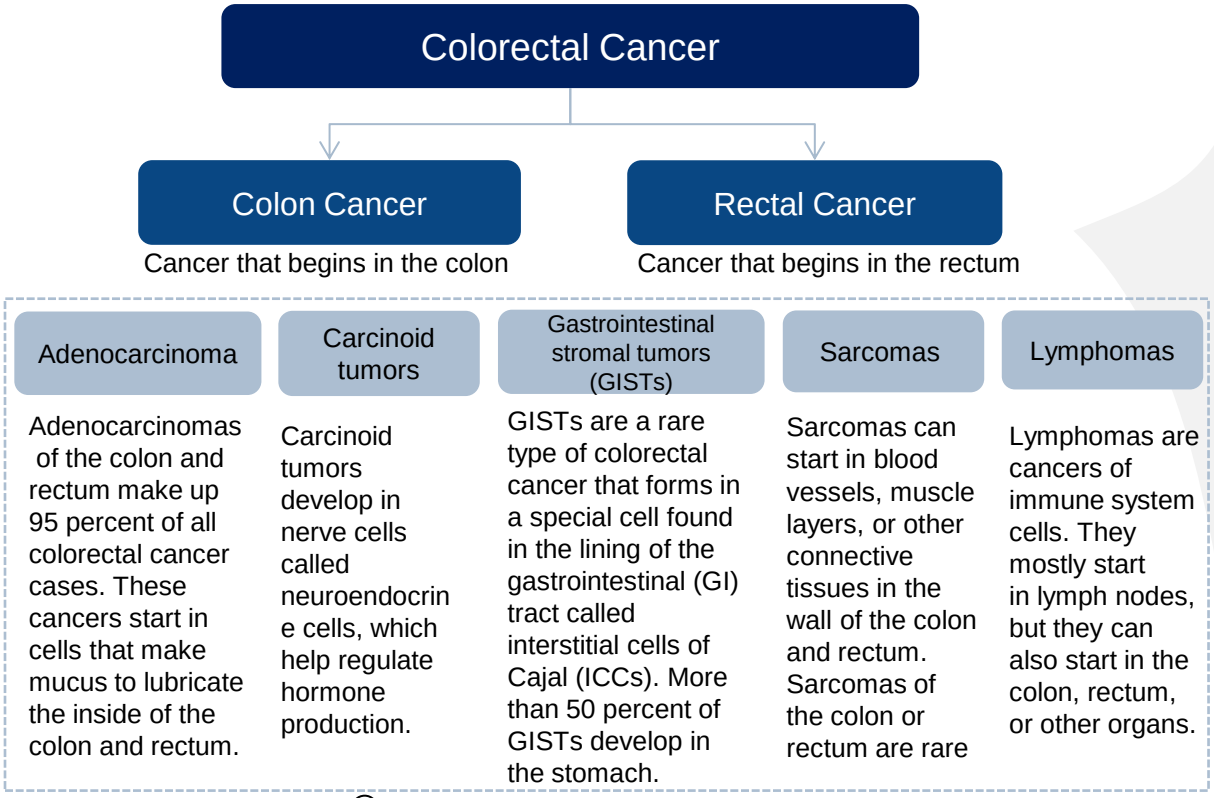
Drug Name	Brand Name	Target	Company	Indications	Approval Date
PENPULIMAB	Anniko	PD-1	AKESO BIOPHARMA	Nasopharyngeal Carcinoma	2025-04-23
Toripalimab	LOQTORZI	PD-1	Coherus BioSciences	Nasopharyngeal Carcinoma	2023-10-27

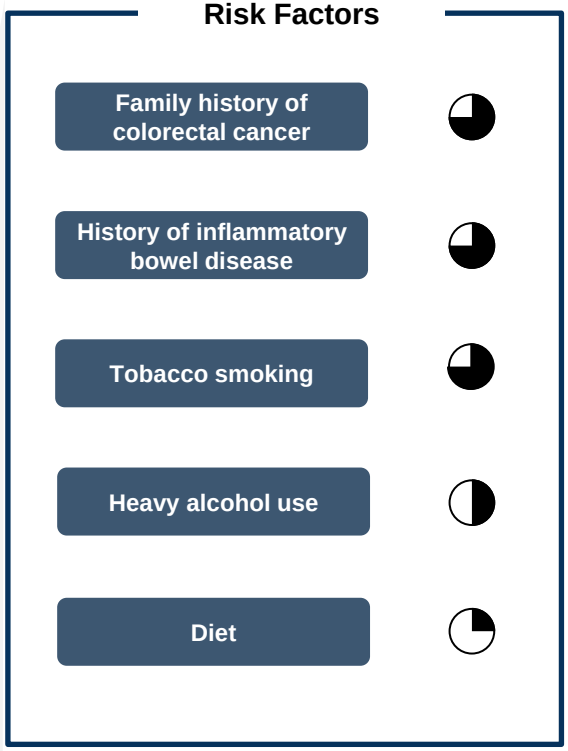
Note: Approval date: First approval date
As of Mya 9th 2025

Source: FDA, Frost & Sullivan Analysis

Overview of Colorectal Cancer

- Colorectal cancer, also known as bowel cancer, colon cancer, or rectal cancer, is any cancer that affects the colon and the rectum. the colon is part of the large intestine or large bowel. The rectum is the passageway that connects the colon to the anus. Most colorectal cancers develop first as polyps, which are abnormal growths inside the colon or rectum that may later become cancerous if they are not removed.
- In China, the incidence and mortality of colorectal cancer rank the 3rd and 5th respectively among all malignant tumors in 2019.





● The most relevant factor ○ The least relevant factor

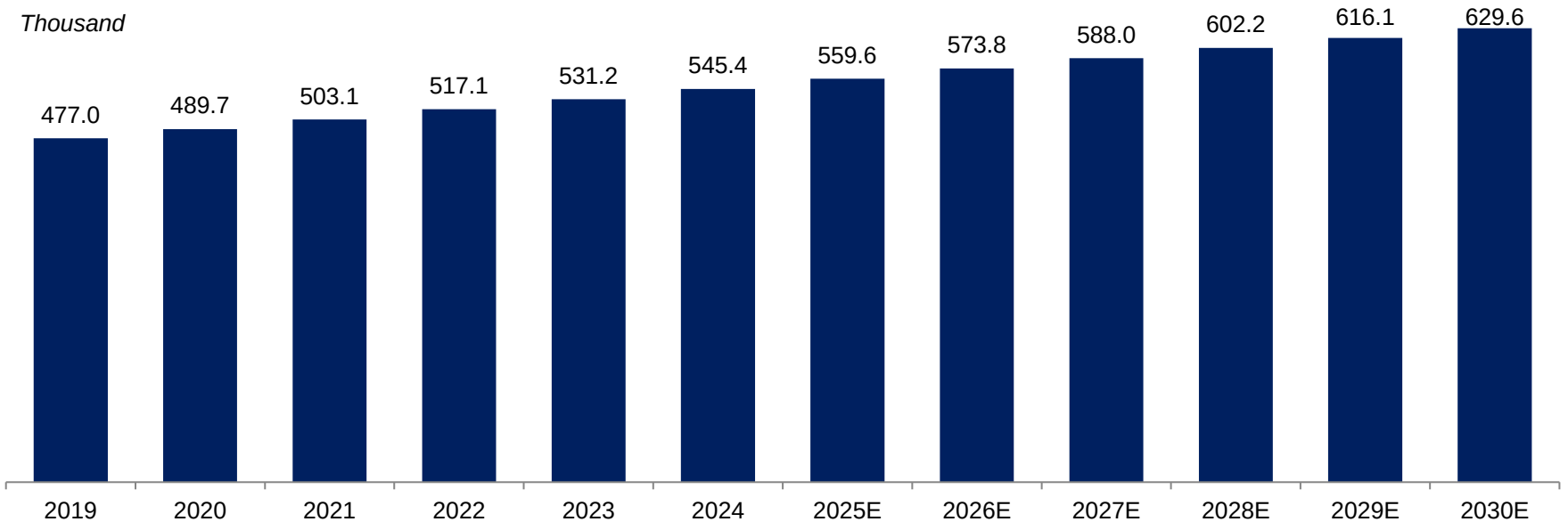
Source: Literature Review, Frost & Sullivan Analysis

Incidence of Colorectal Cancer in China, 2019-2030E

- In China, the number of new cases of colorectal cancer rose to 545.4 thousand in 2024, with a CAGR of 2.7% from 2019. This figure is expected to rise further to 588.0 thousand by 2027, indicating a CAGR of 2.5% from 2024. Projections suggest that the incidence of colorectal cancer will reach an estimated 629.6 thousand cases by 2030, reflecting a CAGR of 2.3% from 2027 to 2030.

Incidence of Colorectal Cancer in China, 2019-2030E

Period	CAGR
2019-2024	2.7%
2024-2027E	2.5%
2027E-2030E	2.3%



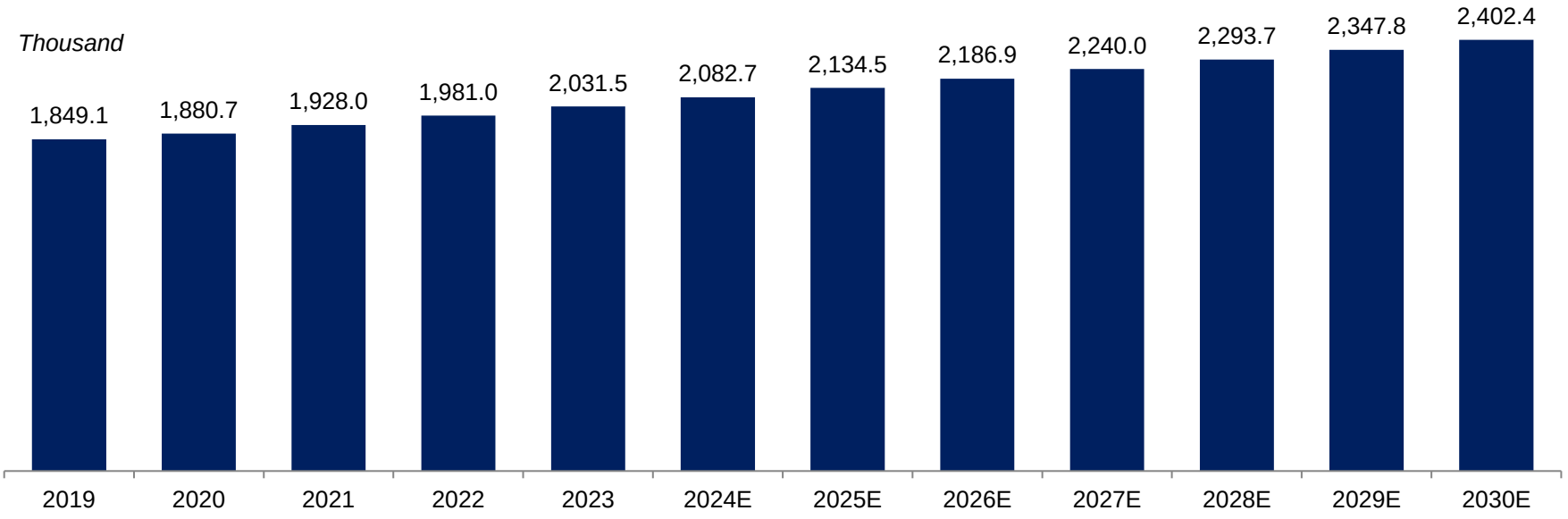
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Colorectal Cancer, 2019-2030E

- Between 2019 and 2023, the global incidence of colorectal cancer increased from 1,849.1 thousand to 2,031.5 thousand, showing a CAGR of 2.4%. Projections suggest that this number will continue to rise to 2,186.9 thousand by 2026, maintaining the same CAGR of 2.5% from 2023 to 2026. By 2030, it is expected to reach 2,402.4 thousand, at a CAGR of 2.4%.

Global Incidence of Colorectal Cancer, 2019-2030E

Period	CAGR
2019-2023	2.4%
2023-2026E	2.5%
2026E-2030E	2.4%



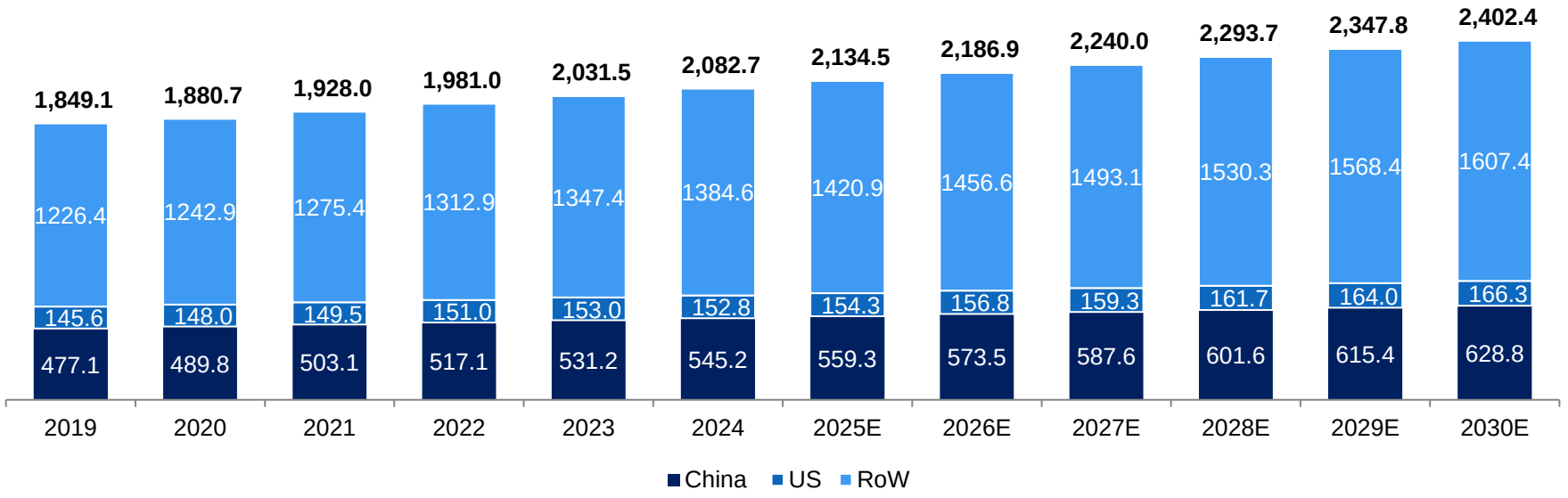
Source: IARC, Frost & Sullivan Analysis

Global Incidence of Colorectal Cancer by Region, 2019-2030E

Global Incidence of Colorectal Cancer by Region, 2019-2030E

Period	CAGR			
	China	US	RoW	Total
2019-2024	2.7%	1.0%	2.5%	2.4%
2024-2030E	2.4%	1.4%	2.5%	2.4%

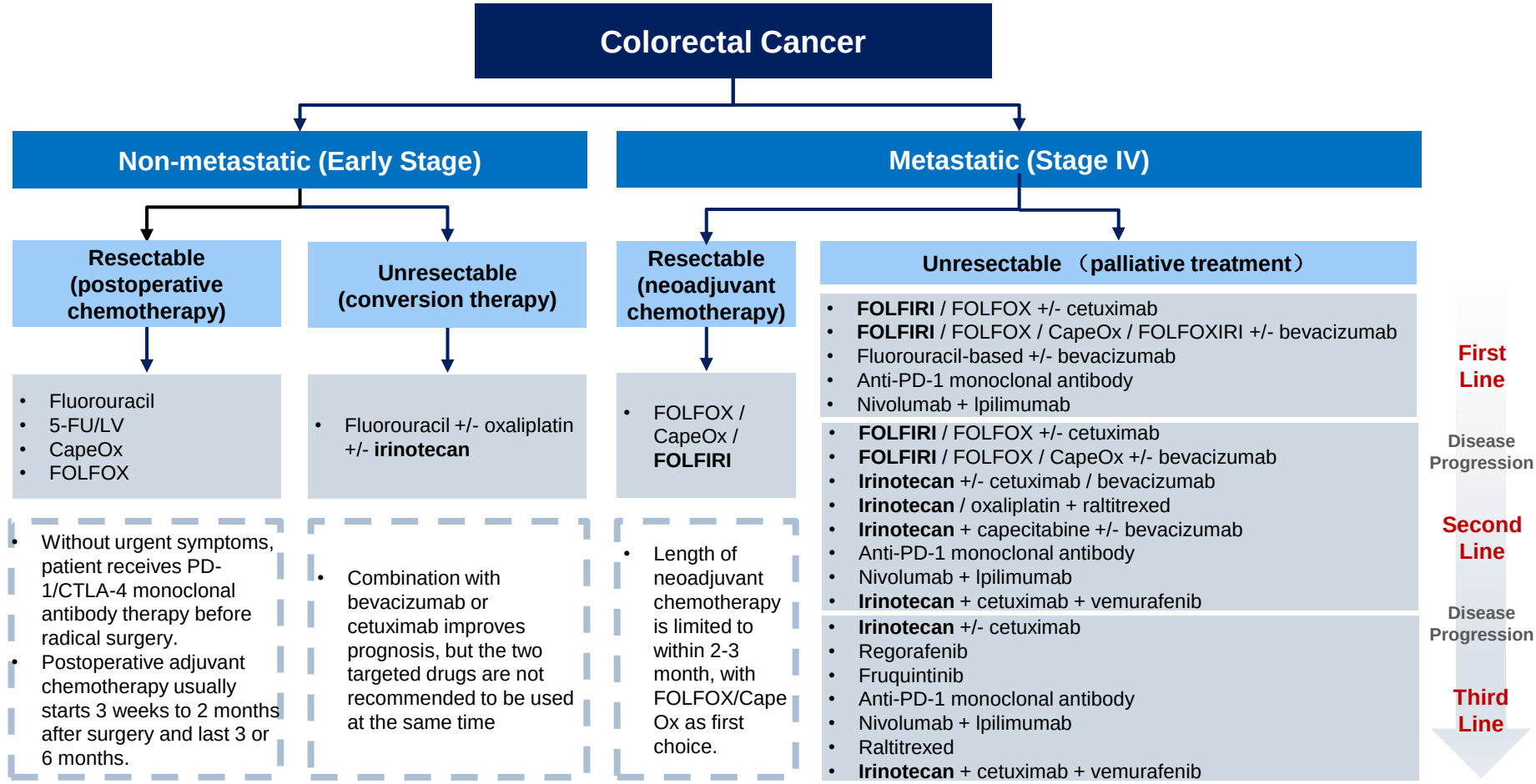
Thousand



Source: IARC, Frost & Sullivan Analysis

Treatment Paradigm of Colorectal Cancer in China

- In China, CSCO guideline on colorectal cancer recommends using CPT analogue drug (irinotecan) in both conversion therapy of non-metastatic unresectable CRC and metastatic CRC.

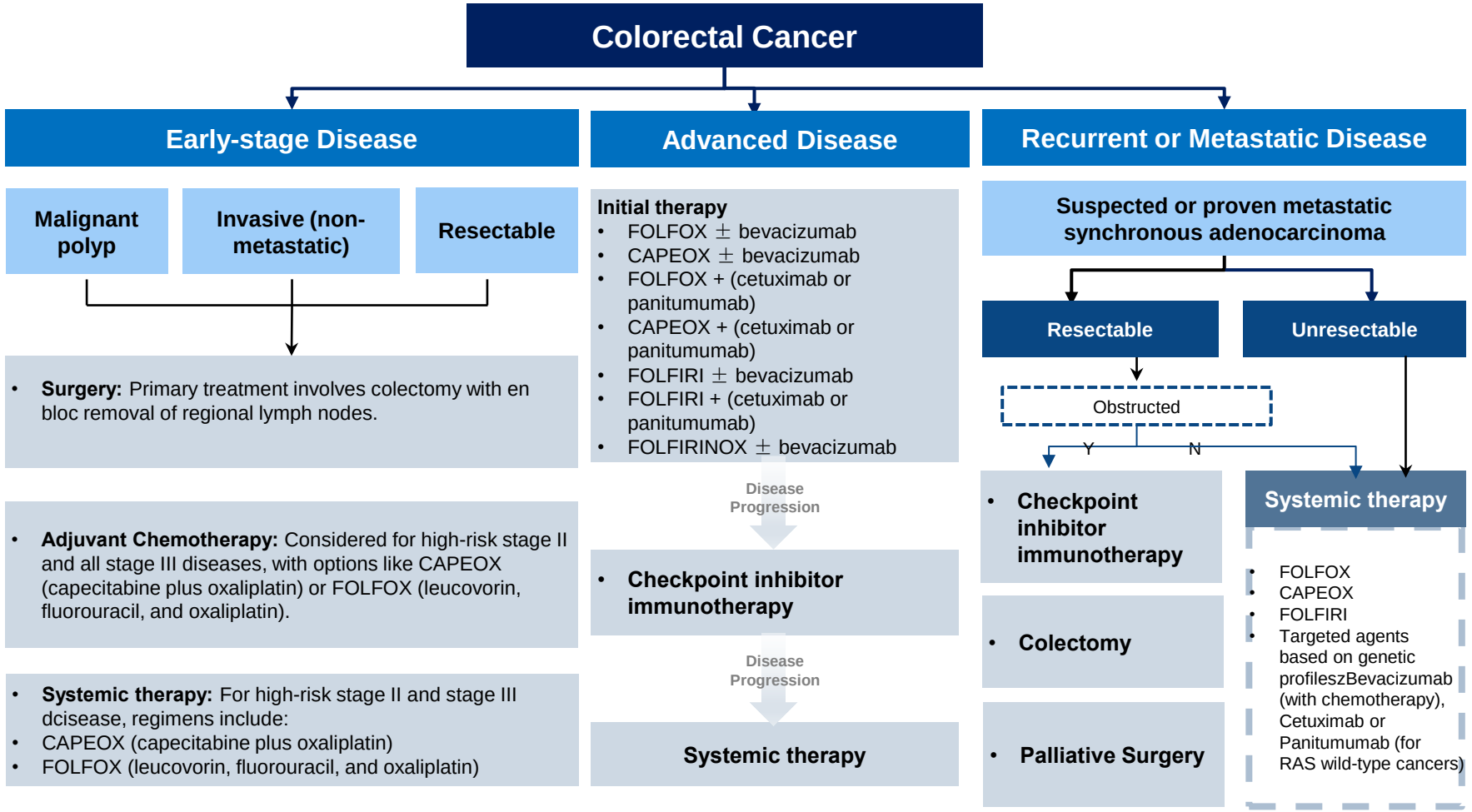


*Notes: 1. FOLFOX=oxaliplatin + leucovorin + 5-FU; **FOLFIRI**=**irinotecan** + leucovorin+ 5-FU; CapeOx=oxaliplatin + capecitabine.*

Source: CSCO 2023, Frost & Sullivan Analysis

Treatment Paradigm of Colorectal Cancer in the U.S.

- Colorectal cancer is a cancer that affects the colon (large intestine) or rectum. It is one of the most common types of cancer worldwide and can cause serious injury and death.



Source: NCCN 2024, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Colorectal Cancer Approved by NMPA

Drug Name	Brand Name	Target	Company	Indication	Approval Date
NIVOLUMAB	OPDIVO	PD-1	BRISTOL MYERS SQUIBB	CRC	2024-10-14
Serplulimab	汉斯状	PD-1	Henlius Biopharmaceutical Co.,LTD	CRC	2022-03-22
Tislelizumab	百泽安	PD-1	Boehringer Ingelheim / BeiGene	CRC	2019-12-26
Pembrolizumab	可瑞达 Keytruda	PD-1	Merck Sharp & Dohme	CRC	2018-07-20
Bevacizumab	安维汀 Avastin	VEGF	Roche	CRC	2010-02-26
Cetuximab	爱必妥 Erbitux	EGFR	Merck	CRC	2005-12-30

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Colorectal Cancer Approved by FDA

Drug Name	Brand Name	Target	Company	Indications	Approval Date
NIVOLUMAB	OPDIVO	PD-1	BRISTOL MYERS SQUIBB	CRC	2014-12-22
PEMBROLIZUMAB	KEYTRUDA	PD-1	MERCK SHARP DOHME	CRC	2014-09-04
RAMUCIRUMAB	CYRAMZA	VEGFR2	ELI LILLY AND CO	CRC	2014-04-21
IPILIMUMAB	YERVOY	CTLA4	BRISTOL MYERS SQUIBB	CRC	2011-03-25
PANITUMUMAB	VECTIBIX	EGFR	AMGEN	CRC	2006-09-27
BEVACIZUMAB	AVASTIN	VEGF	ROCHE	CRC	2004-02-26
CETUXIMAB	ERBITUX	EGFR	IMCLONE	CRC	2004-02-12

Note: Approval date: First approval date
As of Mya 9th 2025

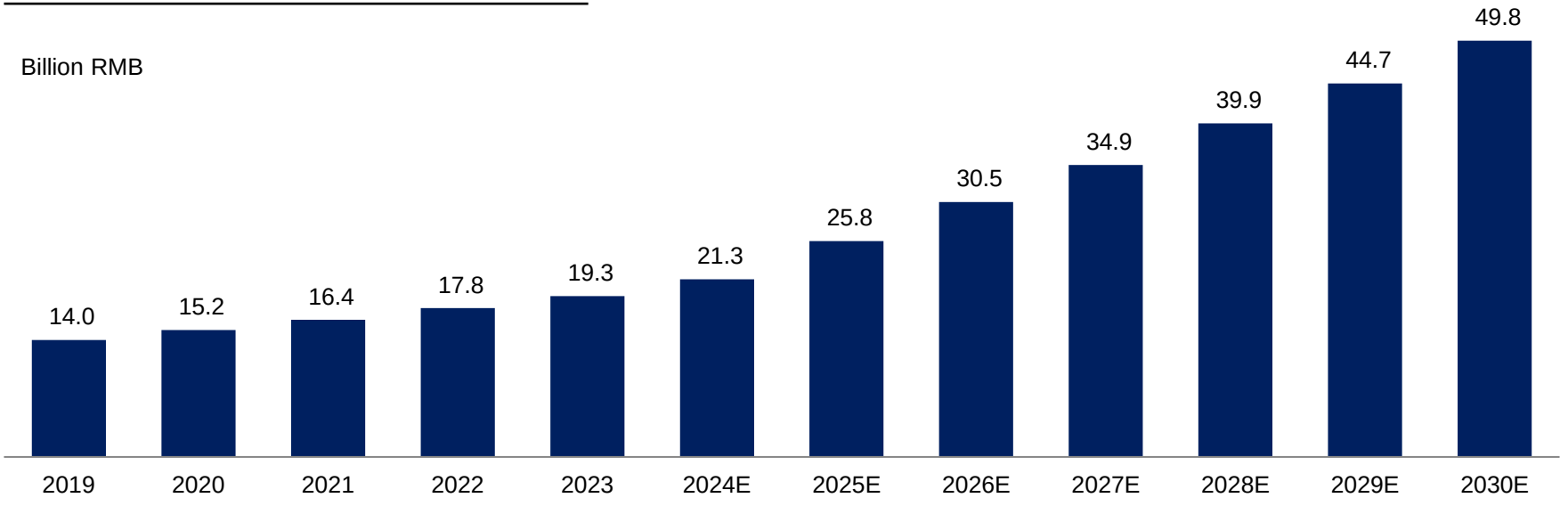
Source: FDA, Frost & Sullivan Analysis

Historical and Forecasted of China CRC Drug Market Size, 2019-2030E

- China's CRC drug market size reached RMB19.3 billion in 2023, with a CAGR of 8.3% from 2019 to 2023. The market size will climb to RMB30.5 billion and RMB49.8 billion in 2026 and 2030 respectively.

Historical and Forecasted of China CRC Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	8.3%
2023-2026E	16.6%
2026E-2030E	13.0%



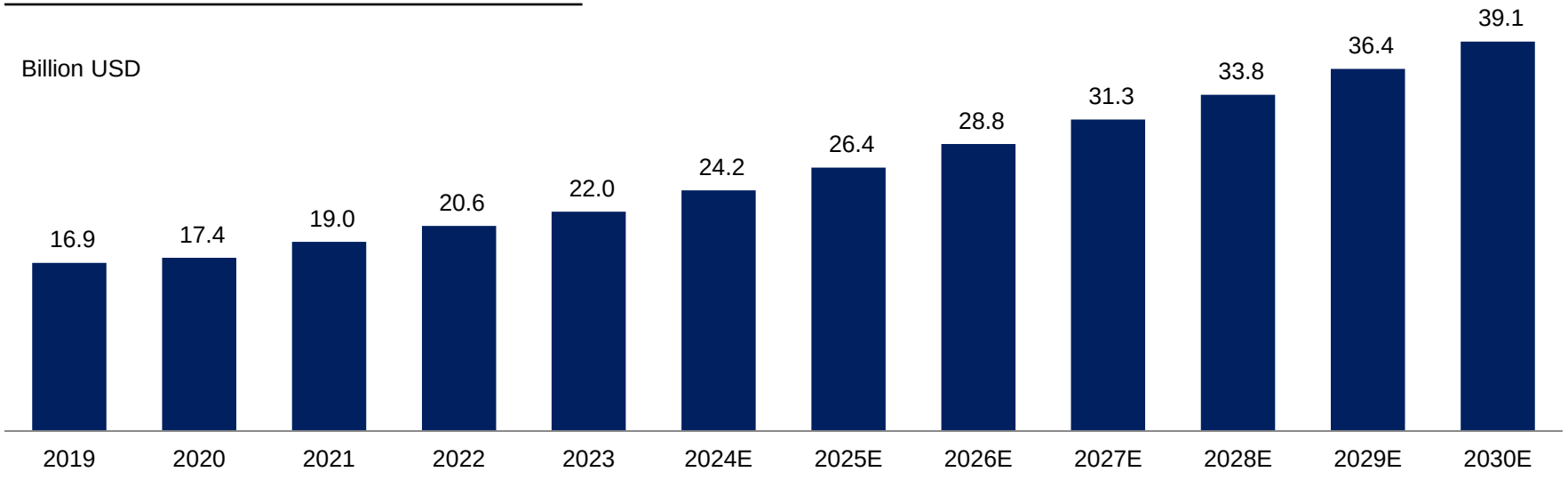
Source: Frost & Sullivan Analysis

Historical and Forecasted of Global CRC Drug Market Size, 2019-2030E

- The global CRC drug market size reached USD22.0 billion in 2023, with a CAGR of 6.9% from 2019 to 2023. The market size is expected to reach USD28.8 billion in 2026, with a CAGR of 9.4% from 2023 to 2026. The market will further grow to USD39.1 billion in 2030, with a CAGR of 7.9% from 2026 to 2030.

Historical and Forecasted of Global CRC Drug Market Size, 2019-2030E

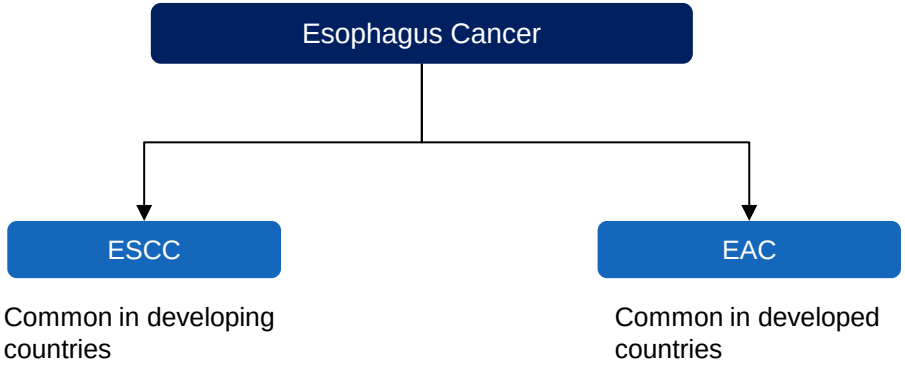
Period	CAGR
2019-2023	6.9%
2023-2026E	9.4%
2026E-2030E	7.9%



Source: Frost & Sullivan Analysis

Overview of Esophagus Cancer

- Esophagus cancer, one of the most common cancer around the world, arises from the lining cells of esophagus.
- Esophageal squamous-cell carcinoma (ESCC) is the predominant histological subtype of esophageal cancer, accounting for approximately 90% of esophageal cancer cases.
- Esophagus cancer cells that derived from different layers of esophagus wall behave differently. There are two main types of esophagus cancer, based on the type of cell it starts in. The esophageal squamous-cell carcinoma(ESCC) is more common in the developing world while the esophageal adenocarcinoma(EAC) is more common in developed countries.



Typical Symptoms

- Trouble swallowing(the most common symptom)
- Chest pain
- Hoarseness
- Weight loss
- Chronic cough
- Vomiting

Risk Factors

Tobacco and alcohol

The use of tobacco products, including cigarettes, cigars, pipes, and chewing tobacco, is a major risk factor for esophageal cancer.

Age

Gender

Men are more likely than women to get esophageal cancer.

Diet

Frequently drinking very hot may increase the risk for the squamous cell type of esophageal cancer.

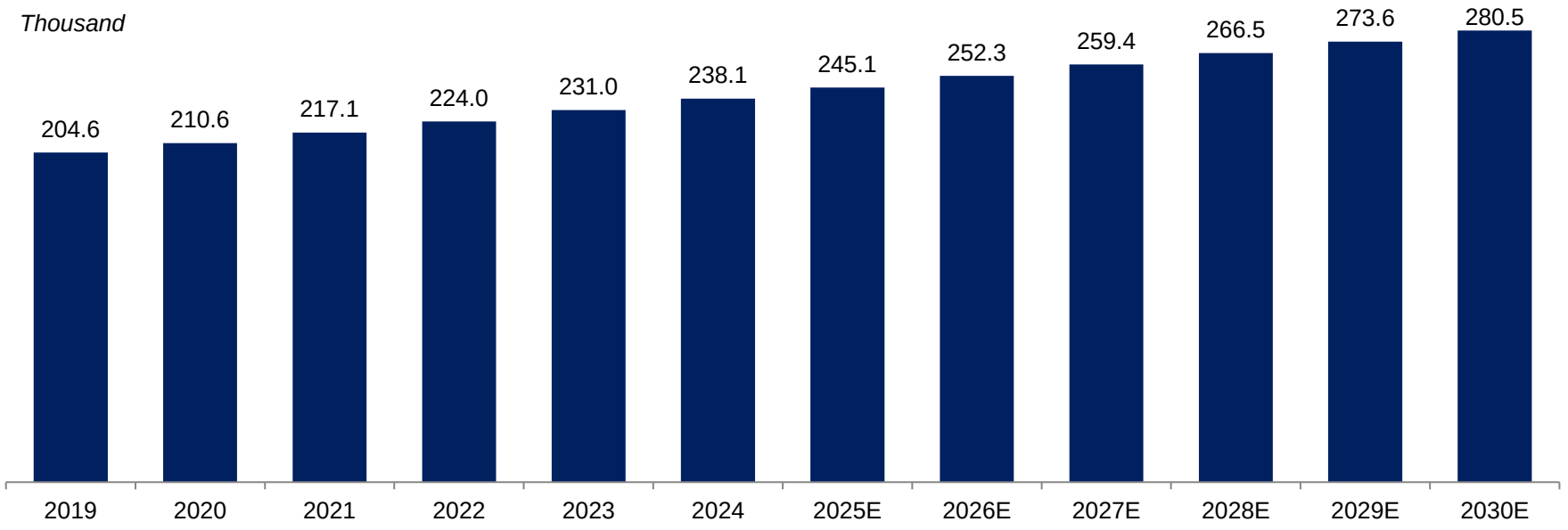
Source: ACS, NCCN Guideline, ESMO Clinical Practice Guidelines, Frost & Sullivan Analysis

Incidence of Esophageal Cancer in China, 2019-2030E

- In China, In China, the number of new cases of esophageal cancer rose to 238.1 thousand in 2024, marking a CAGR of 3.1% from 2019. Projections suggest that this figure will continue to climb to 259.4 thousand by 2027, at a CAGR of 3.1% from 2024. By 2030, it is anticipated that the incidence will reach 280.5 thousand, reflecting a CAGR of 2.6% from 2026 to 2030.

Incidence of Esophageal Cancer in China, 2019-2030E

Period	CAGR
2019-2024	3.1%
2024-2027E	2.9%
2027E-2030E	2.6%



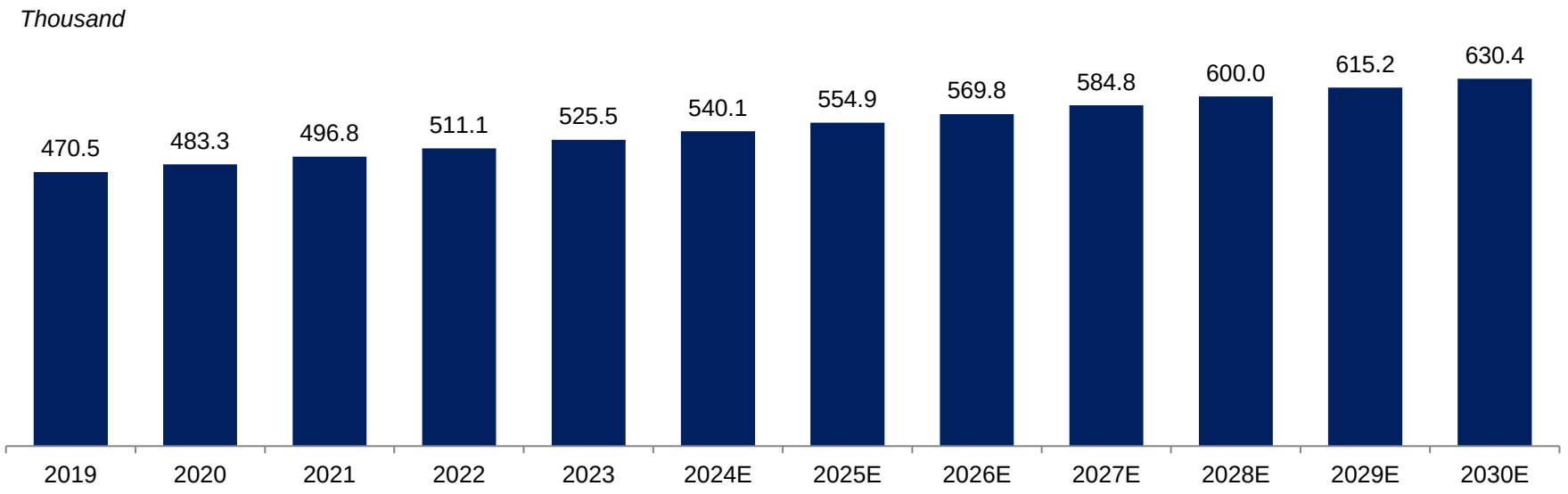
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Esophageal Cancer, 2019-2030E

- Between 2019 and 2023, the global incidence of esophageal cancer increased from 470.5 thousand to 525.5 thousand, showing a CAGR of 2.8%. Projections suggest that this number will continue to rise to 569.8 thousand by 2026, at a CAGR of 2.7% from 2023 to 2026. By 2030, it is expected to reach 630.4 thousand, at CAGR of 2.6%.

Global Incidence of Esophageal Cancer, 2019-2030E

Period	CAGR
2019-2023	2.8%
2023-2026E	2.7%
2026E-2030E	2.6%

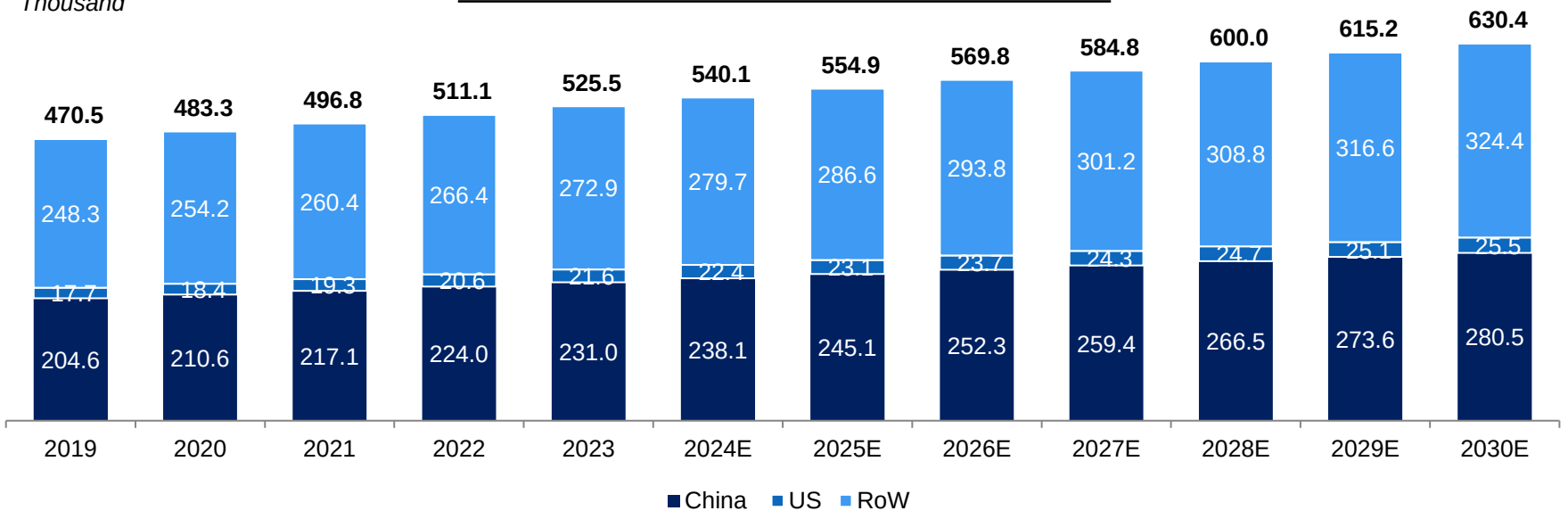


Source: IARC, Frost & Sullivan Analysis

Global Incidence of Esophageal Cancer by Region, 2019-2030E

Global Incidence of Esophageal Cancer by Region, 2019-2030E

Period	CAGR			
	China	US	RoW	Total
2019-2023	3.1%	5.1%	2.4%	2.8%
2023-2026E	3.0%	3.2%	2.5%	2.7%
2026E-2030E	2.7%	1.8%	2.5%	2.6%

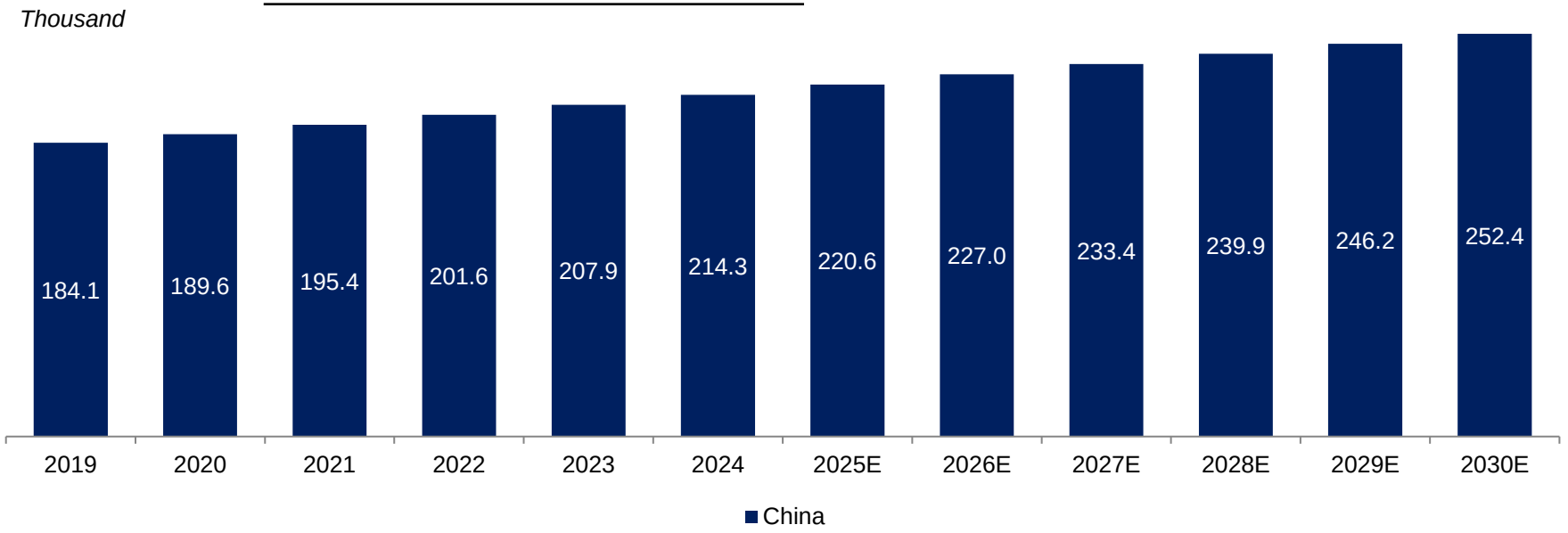


Source: IARC, Frost & Sullivan Analysis

China Incidence of Esophageal Squamous Cell, 2019-2030E

China Incidence of Esophageal Cancer, 2019-2030E

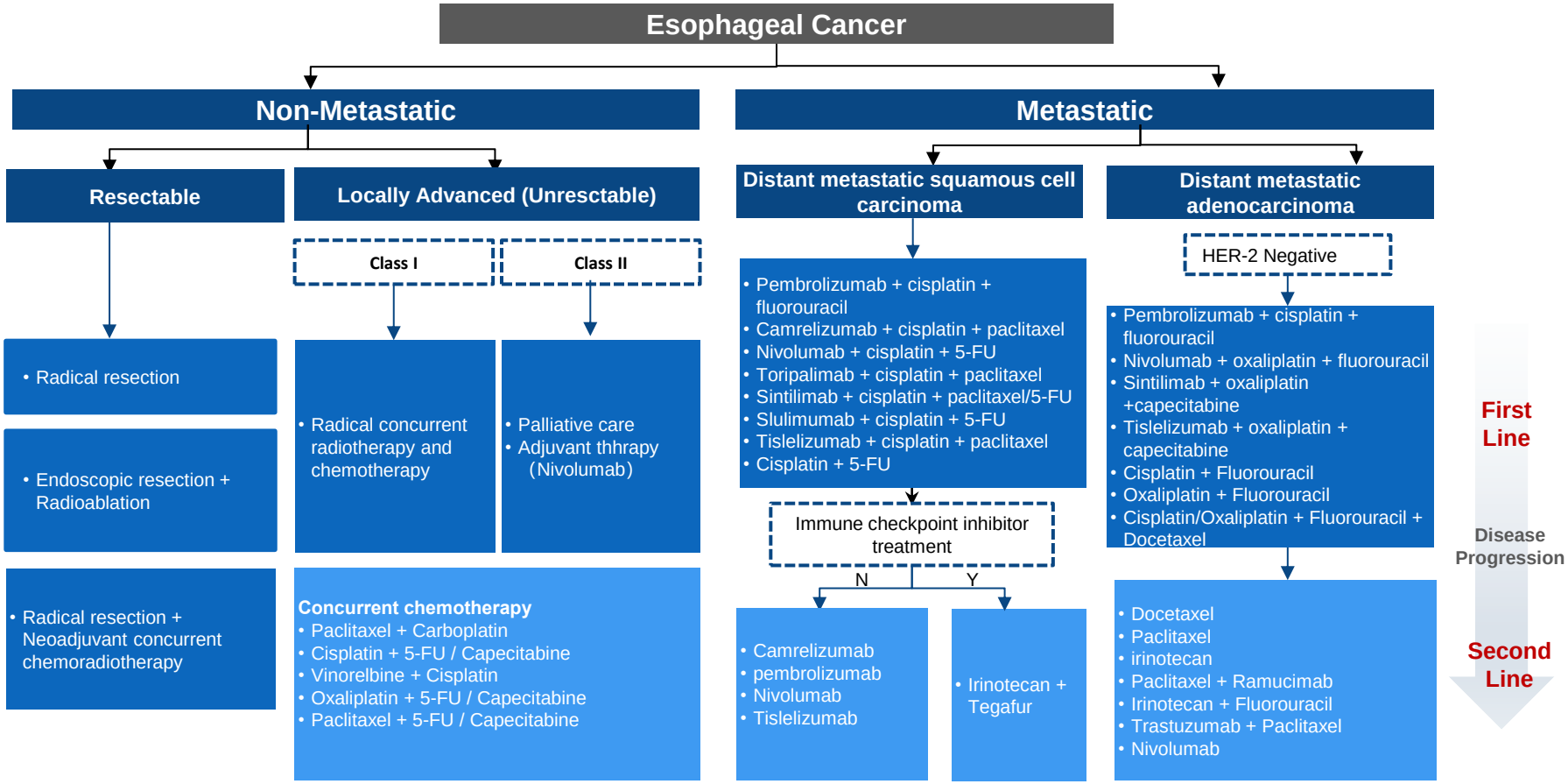
Period	CAGR
2019-2024	3.1%
2024-2027E	2.9%
2027E-2030E	2.6%



Source: IARC, Frost & Sullivan Analysis

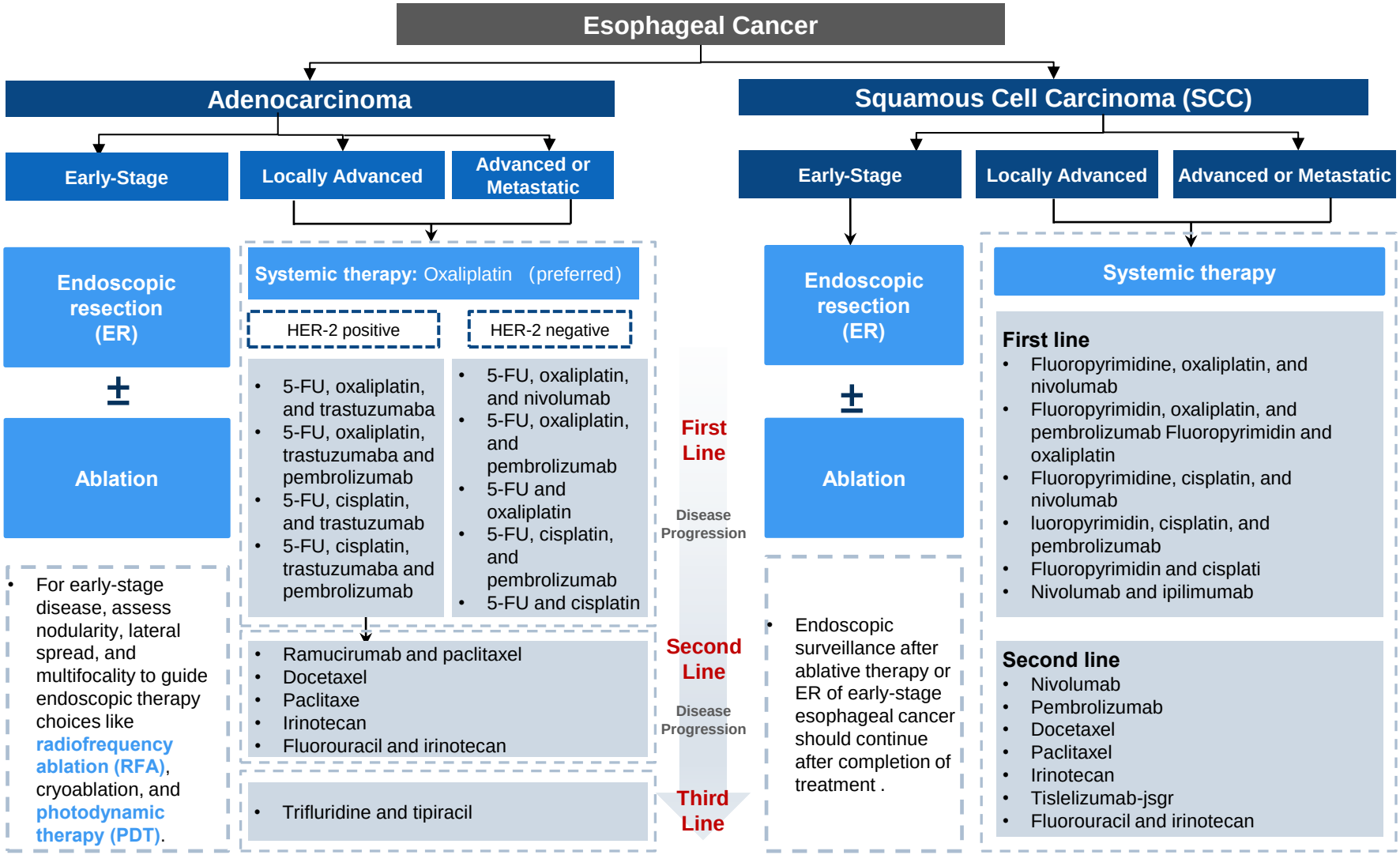
Treatment Paradigm of Esophageal Cancer in China

- Esophageal cancer is one of the common malignant tumors worldwide. Esophageal cancer usually has no obvious specific signs; lymph node enlargement in the neck or supraclavicular area may occur in the middle and late stages, suggesting the possibility of lymph node metastasis; jaundice and hepatomegaly upon palpation Or tenderness in the liver area, etc., indicating the possibility of liver metastasis.



Source: CSCO 2023, Frost & Sullivan Analysis

Treatment Paradigm of Esophageal Cancer in U.S.



Source: NCCN 2024, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Esophageal Cancer Approved by NMPA （1/2）

Drug Name	Brand Name	Target	Company	Indication	Approval Date
Serplulimab	汉斯状	PD-1	Henlius Biopharmaceutical Co.,LTD	Esophageal Cancer	2022-03-22
Ramucirumab	希冉择 Cyramza	VEGFR2	Eli Lilly	Esophageal Cancer	2022-03-16
Sugemalimab	择捷美	PD-L1	Pfizer	Esophageal Cancer	2021-12-20
Tislelizumab	百泽安	PD-1	Boehringer Ingelheim / BeiGene	Esophageal Cancer	2019-12-26
Toripalimab	拓益	PD-1	Junshi Biosciences Co.，Ltd.	Esophageal Cancer	2018-12-17

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Esophageal Cancer Approved by NMPA （2/2）

Drug Name	Brand Name	Target	Company	Indication	Approval Date
Camrelizumab	艾瑞卡	PD-1	Hengrui Medicine Co,.Ltd.	Esophageal Cancer	2019-05-29
Sintilimab	达伯舒	PD-1	Innovent Biologics Co., Ltd.	Esophageal Cancer	2018-12-24
Pembrolizumab	可瑞达 Keytruda	PD-1	Merck Sharp & Dohme	Esophageal Cancer	2018-07-20
Nivolumab	欧狄沃 OPDIVO	PD-1	Bristol Myers Squibb	Esophageal Cancer	2018-06-15
Trastuzumab	赫赛汀 Herceptin	HER2	Roche	Esophageal Cancer	2002-01-01

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Esophageal Cancer Approved by FDA

Drug Name	Brand Name	Target	Company	Indications	Approval Date
ZOLBETUXIMAB	VYLOY	CLDN-18.2	ASTELLAS	Esophageal Cancer	2024-10-18
TISLELIZUMAB	TEVIMBRA	PD-1	BEIGENE	Esophageal Cancer	2024-03-13
NIVOLUMAB	OPDIVO	PD-1	BRISTOL MYERS SQUIBB	Esophageal Cancer	2014-12-22
PEMBROLIZUMAB	KEYTRUDA	PD-1	MERCK SHARP DOHME	Esophageal Cancer	2014-09-04
RAMUCIRUMAB	CYRAMZA	VEGFR2	ELI LILLY AND CO	Esophageal Cancer	2014-04-21
TRASTUZUMAB	HERCEPTIN	HER2	GENENTECH	Esophageal Cancer	1998-09-25

Note: Approval date: First approval date
As of Mya 9th 2025

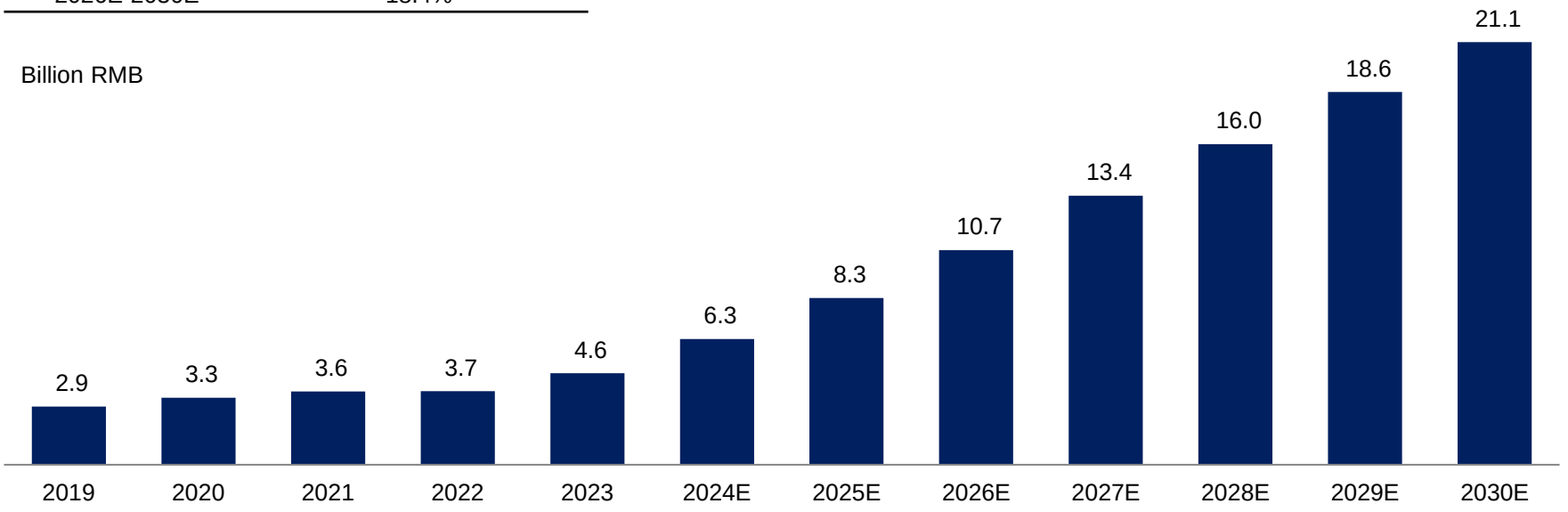
Source: FDA, Frost & Sullivan Analysis

Historical and Forecasted of China Esophagus Cancer Drug Market Size, 2019-2030E

- China's esophagus cancer drug market size reached RMB4.6 billion in 2023, with a CAGR of 11.9% from 2019 to 2023. The market size will climb to RMB10.7 billion and RMB21.1 billion in 2026 and 2030 respectively.

Historical and Forecasted of China Esophagus Cancer Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	11.9%
2023-2026E	32.9%
2026E-2030E	18.4%



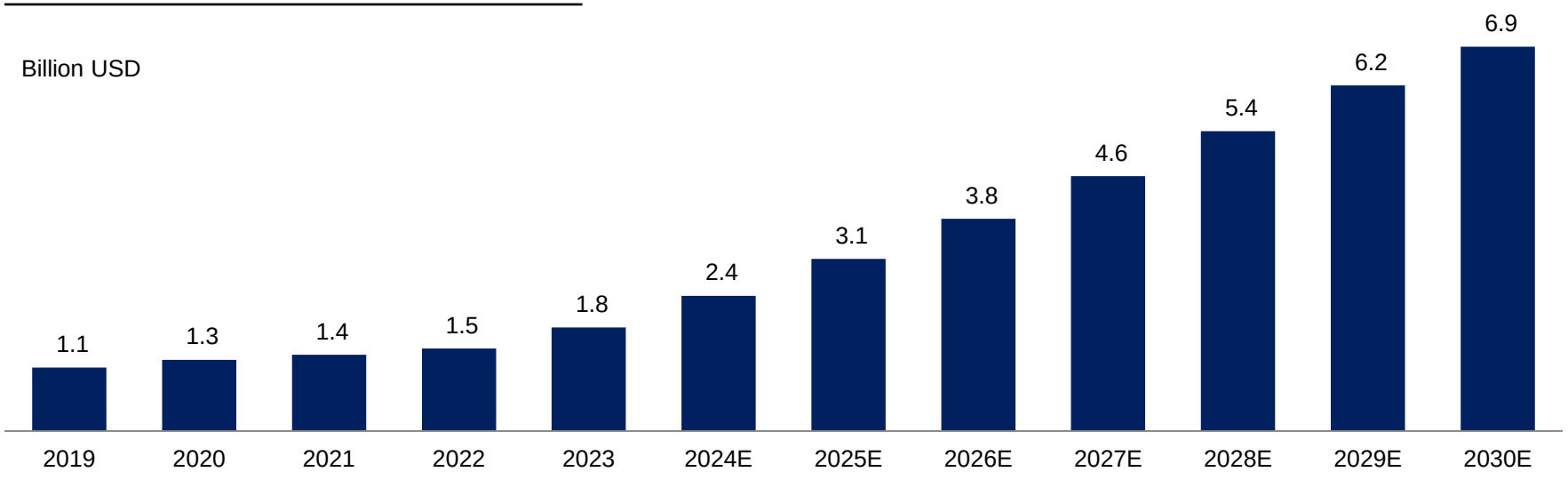
Source: Frost & Sullivan Analysis

Historical and Forecasted of Global Esophagus Cancer Drug Market Size, 2019-2030E

- The global esophagus cancer drug market size reached USD1.8 billion in 2023, with a CAGR of 13.1% from 2019 to 2023. The market size is expected to reach USD3.8 billion in 2026, with a CAGR of 27.0% from 2023 to 2026. The market will further grow to USD6.9 billion in 2030, with a CAGR of 16.0% from 2026 to 2030.

Historical and Forecasted of Global Esophagus Cancer Drug Market Size, 2019-2030E

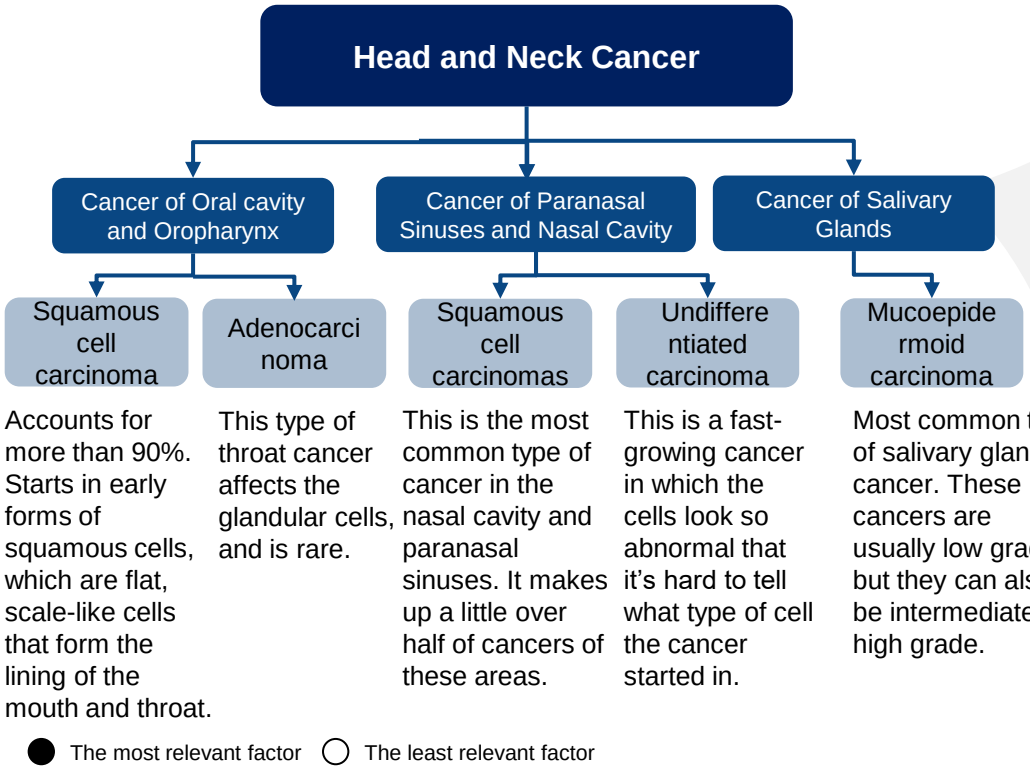
Period	CAGR
2019-2023	13.1%
2023-2026E	27.0%
2026E-2030E	16.0%

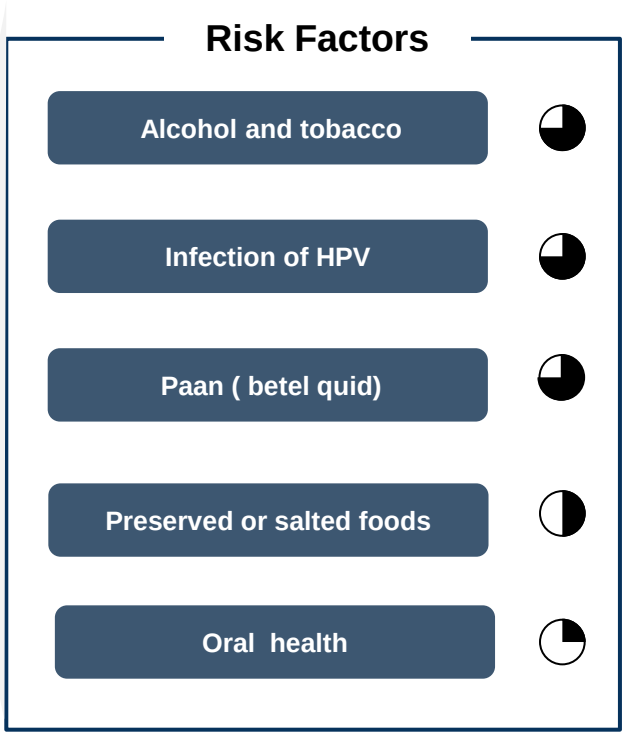


Source: Frost & Sullivan Analysis

Overview of Head and Neck Cancer

- Head and neck cancer is a group of cancers that starts in the mouth, nose, throat, larynx, sinuses, or salivary glands. About 75% of head and neck cancer is caused by the use of alcohol or tobacco.
- Symptoms for head and neck cancer may include a lump or sore that does not heal, a sore throat that does not go away, trouble swallowing, or a change in the voice. There may also be unusual bleeding, facial swelling, or trouble breathing.





Source: Frost & Sullivan Analysis

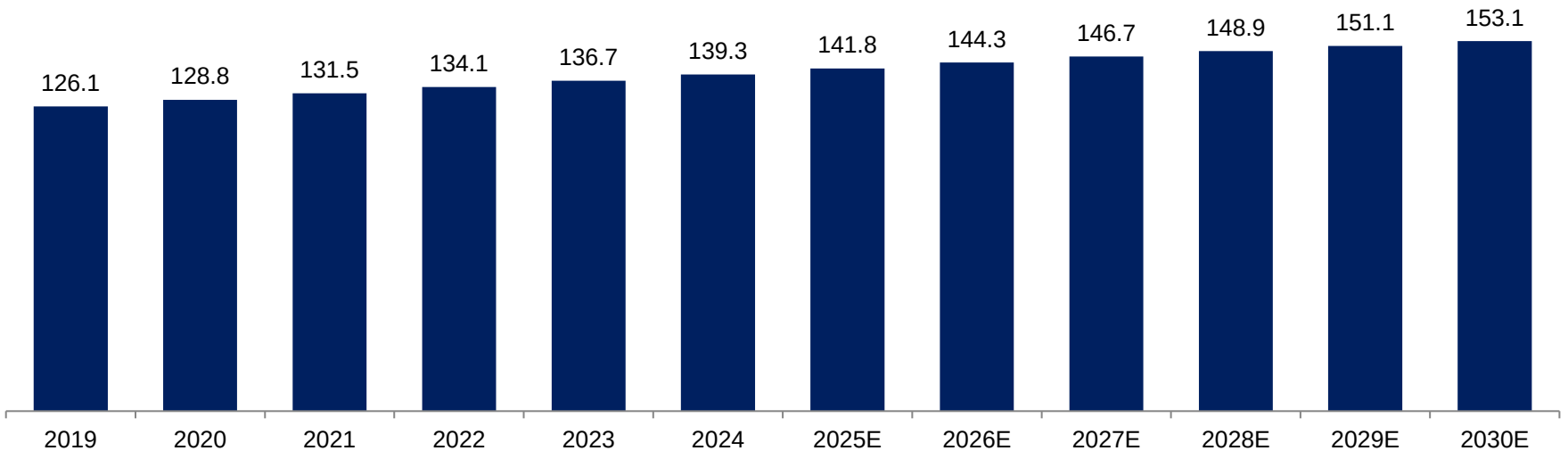
Incidence of Head and Neck Squamous Cell Carcinoma in China, 2019-2030E

- In China, In China, the number of new cases of head and neck squamous cell carcinoma rose to 139.3 thousand in 2024, marking a CAGR of 2.0% from 2019. Projections suggest that this figure will continue to climb to 146.7 thousand by 2027, at a CAGR of 1.7% from 2024. By 2030, it is anticipated that the incidence will reach 153.1 thousand, reflecting a CAGR of 1.4% from 2027 to 2030.

Incidence of Head and Neck Squamous Cell Carcinoma in China, 2019-2030E

Period	CAGR
2019-2024	2.0%
2024-2027E	1.7%
2027E-2030E	1.4%

Thousand



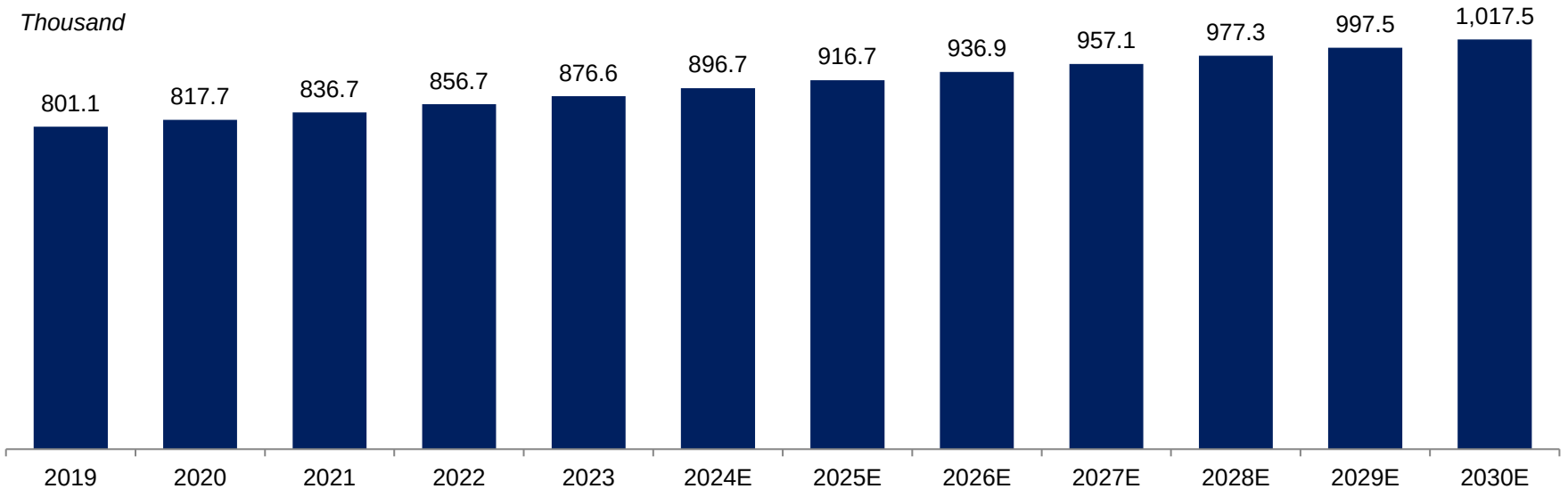
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Head and Neck Squamous Cell Carcinoma, 2019-2030E

- Between 2019 and 2023, the global incidence of head and neck squamous cell carcinoma increased from 801.1 thousand to 876.6 thousand, showing a CAGR of 2.3%. Projections suggest that this number will continue to rise to 936.9 thousand by 2026, maintaining the same CAGR of 2.2% from 2023 to 2026. By 2030, it is expected to reach 1017.5 thousand at a CAGR of 2.1%.

Global Incidence of Head and Neck Squamous Cell Carcinoma, 2019-2030E

Period	CAGR
2019-2023	2.3%
2023-2026E	2.2%
2026E-2030E	2.1%



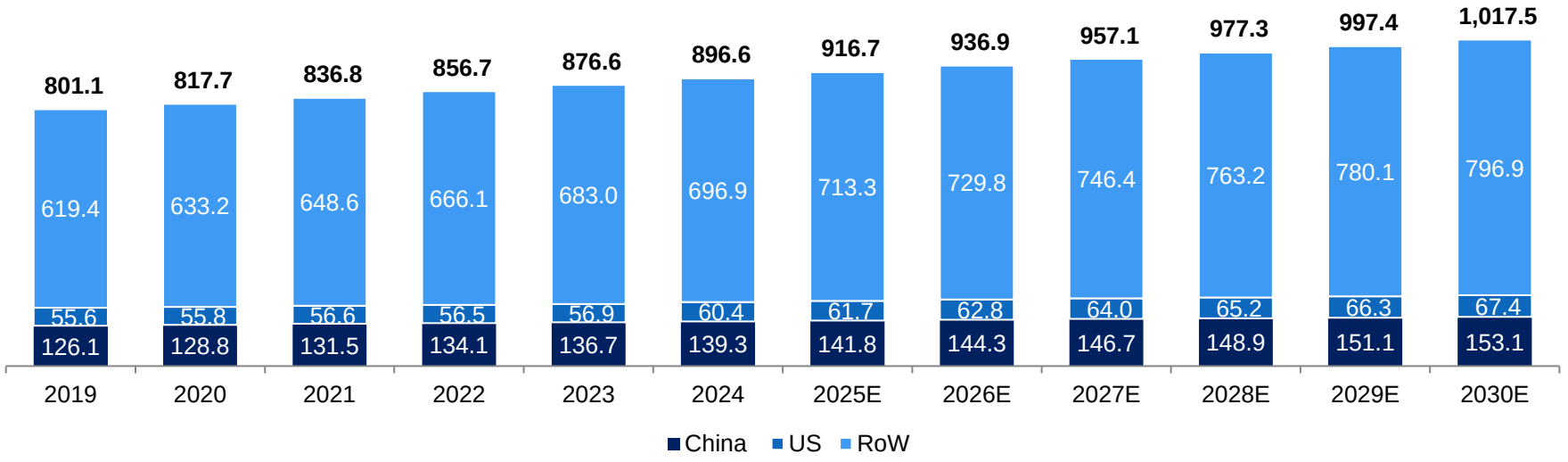
Source: IARC, Frost & Sullivan Analysis

Global Incidence of Head and Neck Squamous Cell Cancer by Region, 2019-2030E

Global Incidence of Head and Neck Squamous Cell Cancer by Region, 2019-2030E

Period	CAGR			
	China	US	RoW	Total
2019-2024	2.0%	1.7%	2.4%	2.3%
2026E-2030E	1.6%	1.8%	2.3%	2.1%

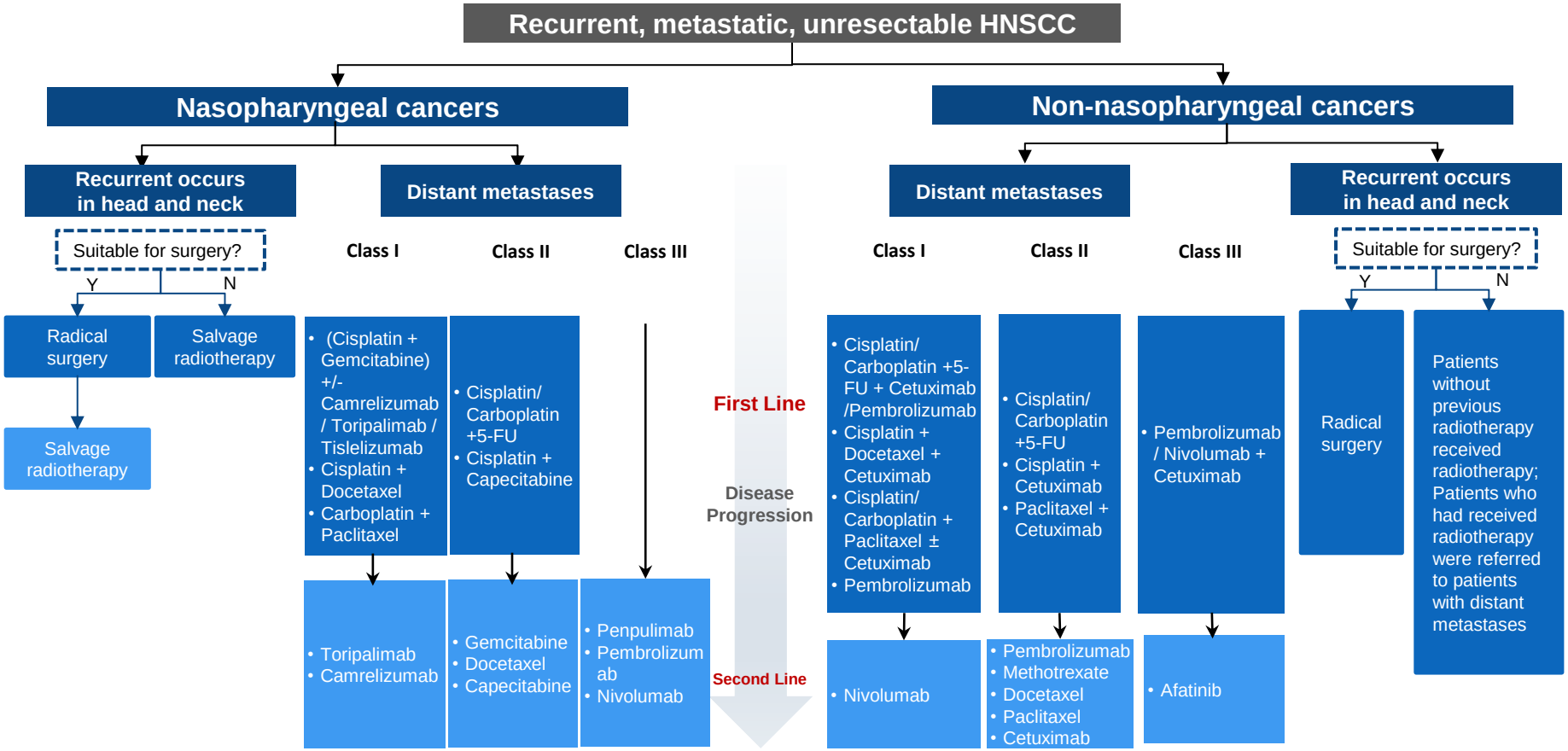
Thousand



Source: IARC, Frost & Sullivan Analysis

Treatment Paradigm of HNSCC in China

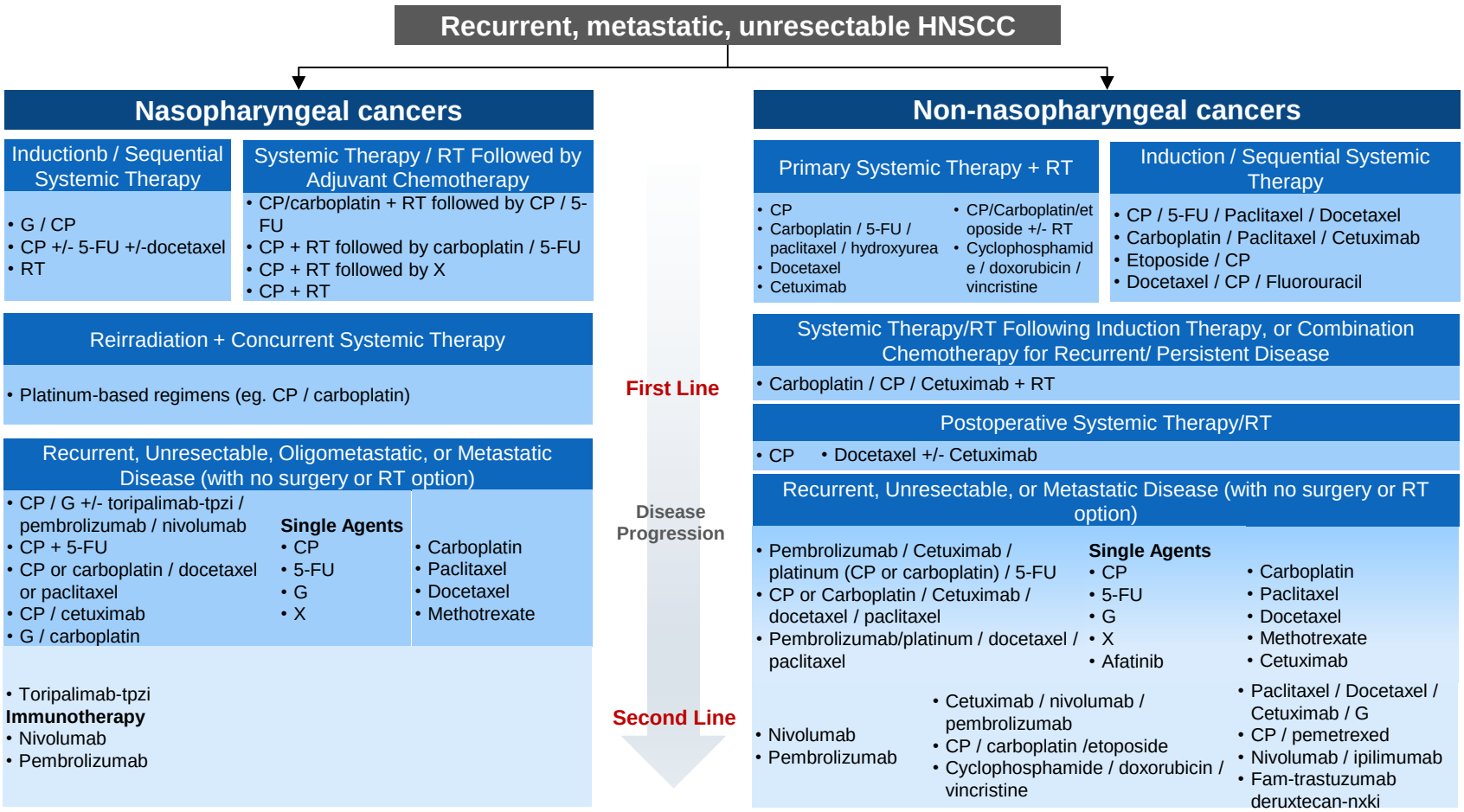
- For HNSCC, the most common subtype of head and neck cancer, patients can be divided into different treatment paths depending on whether they are nasopharyngeal cancer. For patients with recurrent HNSCC (non-metastatic), whether for the primary lesion or cervical lymph nodes, radical surgery is the common treatment, and for patients who are not suitable for surgery, salvage radiotherapy and other treatments will be used. Palliative chemotherapy is the treatment for most metastatic HNSCC.



Note: Unsuitable surgery means that the patient's physical condition does not permit, CSCO refuses surgery for various reasons, or the tumor is too large to resect.

Source: CSCO2023, Literature Review, Frost & Sullivan Analysis

Treatment Paradigm of HNSCC in the U.S.



Notes: RT=Radiation therapy; CP = cisplatin; X = capecitabine; 5-FU = 5-Fluorouracil; G = gemcitabine

Source: NCCN2024, Literature Review, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Head and Neck Cancer Approved by NMPA

Drug Name	Brand Name	Target	Company	Indication	Approval Date
Finotonlimab	安佑平	PD-1	SinoCelltech Ltd.	HNC	2025-02-08
Nivolumab	欧狄沃	PD-1	Bristol-Myers Squibb Pharma EEIG	HNC	2024-10-14
Penpulimab	安尼可	PD-1	Akeso / Chiatai Tianqing Pharmaceutical Group	HNC	2021-08-03
Tislelizumab	百泽安	PD-1	Boehringer Ingelheim / BeiGene	HNC	2019-12-26
Camrelizumab	艾瑞卡	PD-1	Hengrui Medicine Co,.Ltd.	HNC	2019-05-29
Toripalimab	拓益	PD-1	Junshi Biosciences Co.，Ltd.	HNC	2018/12/17
Pembrolizumab	可瑞达 Keytruda	PD-1	Merck Sharp & Dohme	HNC	2018-07-20
Nivolumab	欧狄沃 OPDIVO	PD-1	Bristol Myers Squibb	HNC	2018-06-15
Nimotuzumab	泰欣生	EGFR	Biotech Pharmaceuticals Co., Ltd.	HNC	2008-01-07
Cetuximab	爱必妥 Erbitux	EGFR	Merck	HNC	2005-12-30

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Head and Neck Cancer Approved by FDA

Drug Name	Brand Name	Target	Company	Indications	Approval Date
PENPULIMAB	Anniko	PD-1	AKESO BIOPHARMA	Nasopharyngeal Carcinoma	2025-04-23
TORIPALIMAB	LOQTORZI	PD-1	COHERUS BIOSCIENCES INC	HNC	2023-10-27
NIVOLUMAB	OPDIVO	PD-1	BRISTOL MYERS SQUIBB	HNC	2014-12-22
PEMBROLIZUMAB	KEYTRUDA	PD-1	MERCK SHARP DOHME	HNC	2014-09-04
CETUXIMAB	ERBITUX	EGFR	IMCLONE	HNC	2004-02-12

Note: Approval date: First approval date
As of Mya 9th 2025

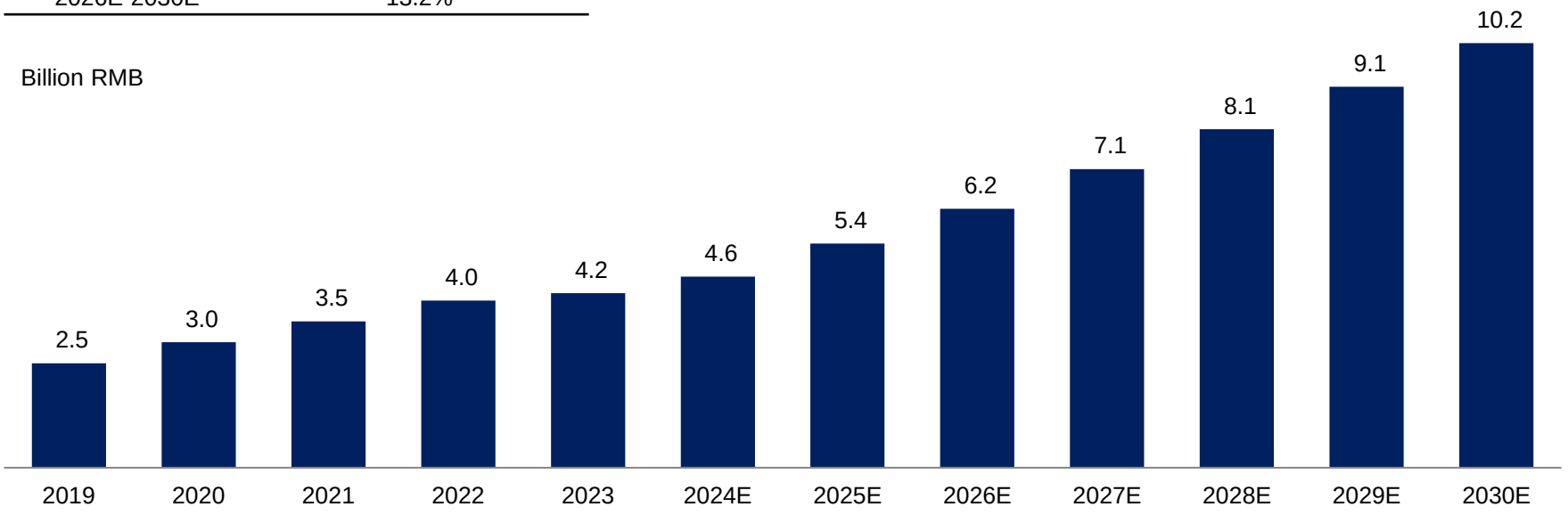
Source: FDA, Frost & Sullivan Analysis

Historical and Forecasted of China Head and Neck Cancer Drug Market Size, 2019-2030E

- China's head and neck cancer drug market size reached RMB4.2 billion in 2023, with a CAGR of 13.7% from 2019 to 2023. The market size will climb to RMB6.2 billion and RMB10.2 billion in 2026 and 2030 respectively.

Historical and Forecasted of China Head and Neck Cancer Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	13.7%
2023-2026E	14.1%
2026E-2030E	13.2%



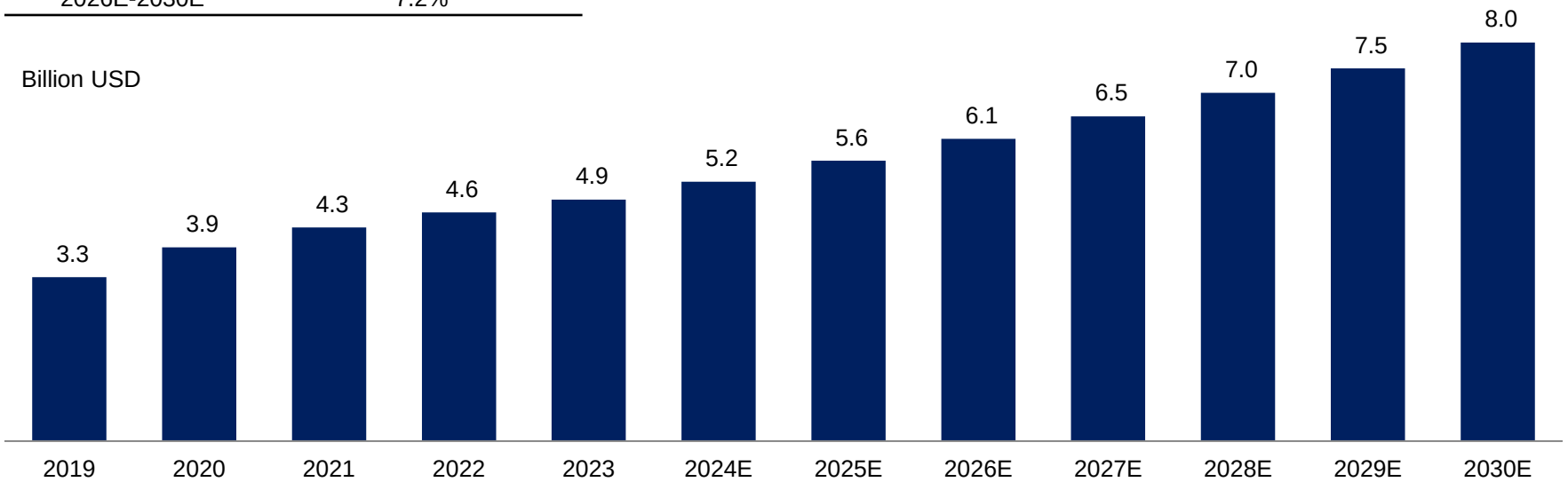
Source: Frost & Sullivan Analysis

Historical and Forecasted of Global Head and Neck Cancer Drug Market Size, 2019-2030E

- The global head and neck cancer drug market size reached USD4.9 billion in 2023, with a CAGR of 10.2% from 2019 to 2023. The market size is expected to reach USD6.1 billion in 2026, with a CAGR of 7.8% from 2023 to 2026. The market will further grow to USD8.0 billion in 2030, with a CAGR of 7.2% from 2026 to 2030.

Historical and Forecasted of Global Head and Neck Cancer Drug Market Size, 2019-2030E

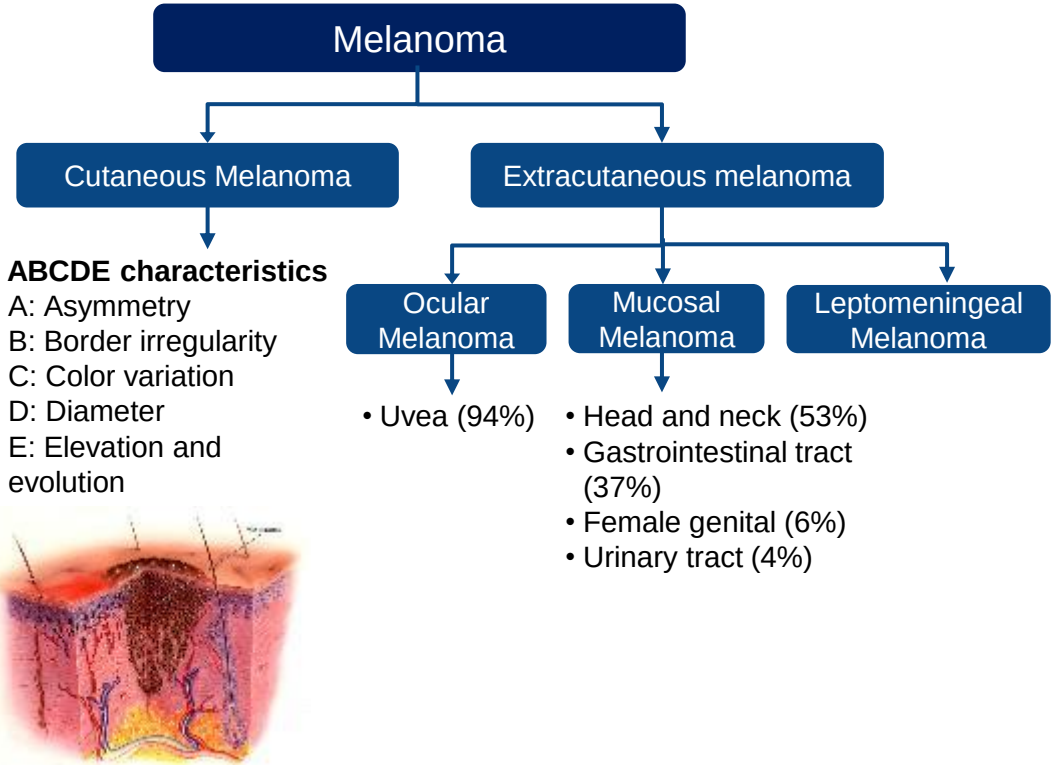
Period	CAGR
2019-2023	10.2%
2023-2026E	7.8%
2026E-2030E	7.2%

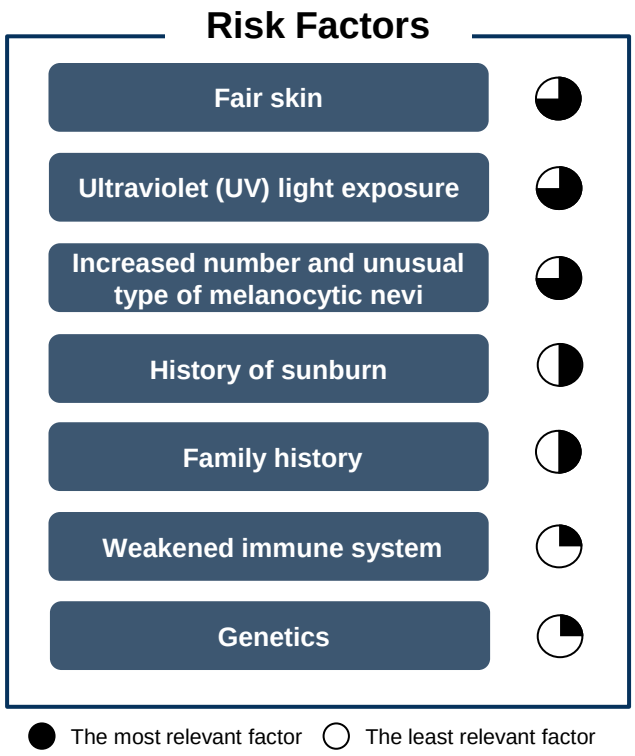


Source: Frost & Sullivan Analysis

Overview of Melanoma

- Melanoma is the most serious type of skin cancer and it can also form in eyes and inside the body, such as in the nose or throat. It develops in melanocytes – the cells that produce the pigment melanin that colors the skin, hair and eyes.
- Signs and symptoms are often new spots or moles on the skin which change in size, shape, and color. The spot can cause bleeding and looks different from other lesions. Important signs include skin sore that doesn't heal and moles that are red, swollen, itchy, tender, bleeding, or painful.
- Diagnosis is based on clinical manifestation, physical exam and biopsy. For more-advanced melanoma, imaging tests including CT, MRI, PET-CT, ultrasound, and isotope bone scans are recommend to look for signs of metastasis.





Source: Literature Review, Frost & Sullivan Analysis

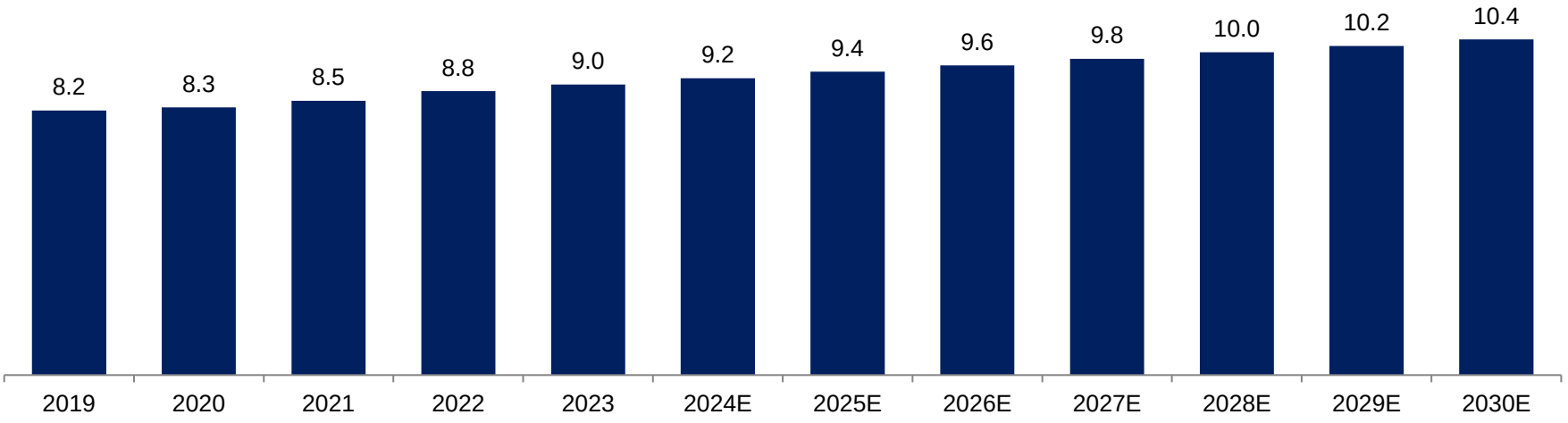
Incidence of Melanoma of Skin China, 2019-2030E

- In China, new case of melanoma of skin reached 9.0 thousand in 2023 at a CAGR of 2.4% from 2019. It is projected to further increase to 9.6 thousand in 2026, representing a CAGR of 2.2% from 2023. It is estimated that the incidence would achieve 10.4 thousand in 2030, representing a CAGR of 2.0% from 2026 to 2030.

Incidence of Melanoma of Skin in China, 2019-2030E

Period	CAGR
2019-2023	2.4%
2023-2026E	2.2%
2026E-2030E	2.0%

Thousand



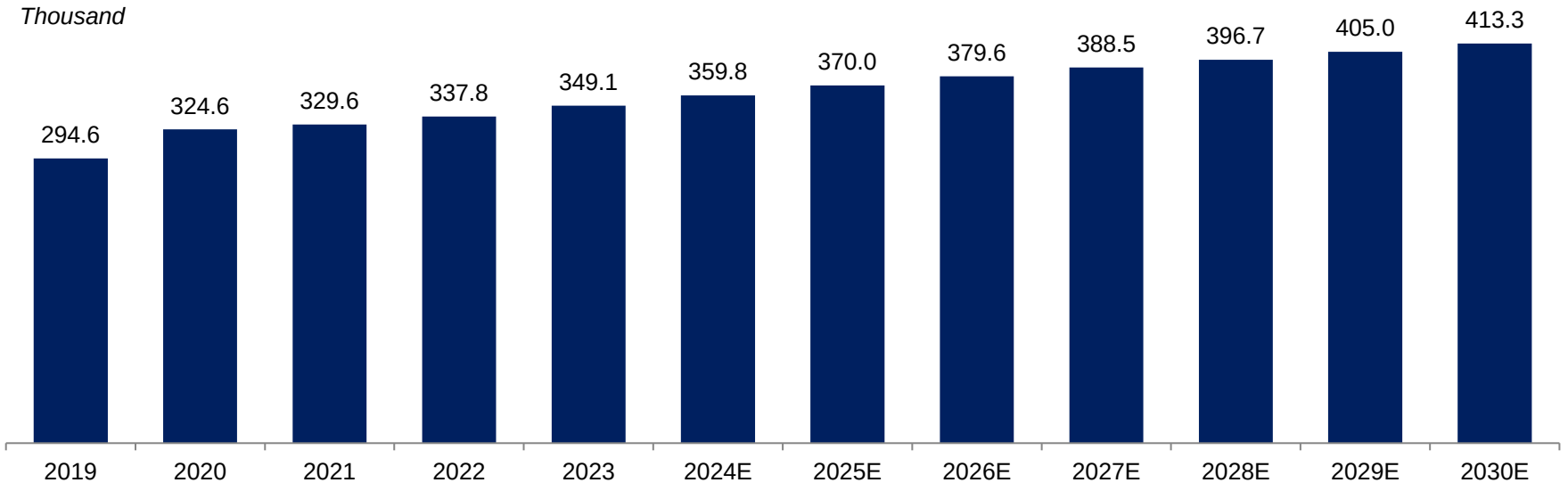
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Melanoma of Skin, 2019-2030E

- From 2019 to 2023, the worldwide incidence of melanoma of skin saw an uptick from 294.6 thousand to 349.1 thousand cases, indicating a CAGR of 4.3%. Forecasts indicate that this figure is poised to further climb to 379.6 thousand by 2026, holding steady at a CAGR of 2.8% from 2023 to 2026. By the year 2030, it is anticipated to reach 413.3 thousand cases, at a CAGR of 2.1%.

Global Incidence of Melanoma of Skin, 2019-2030E

Period	CAGR
2019-2023	4.3%
2023-2026E	2.8%
2026E-2030E	2.1%

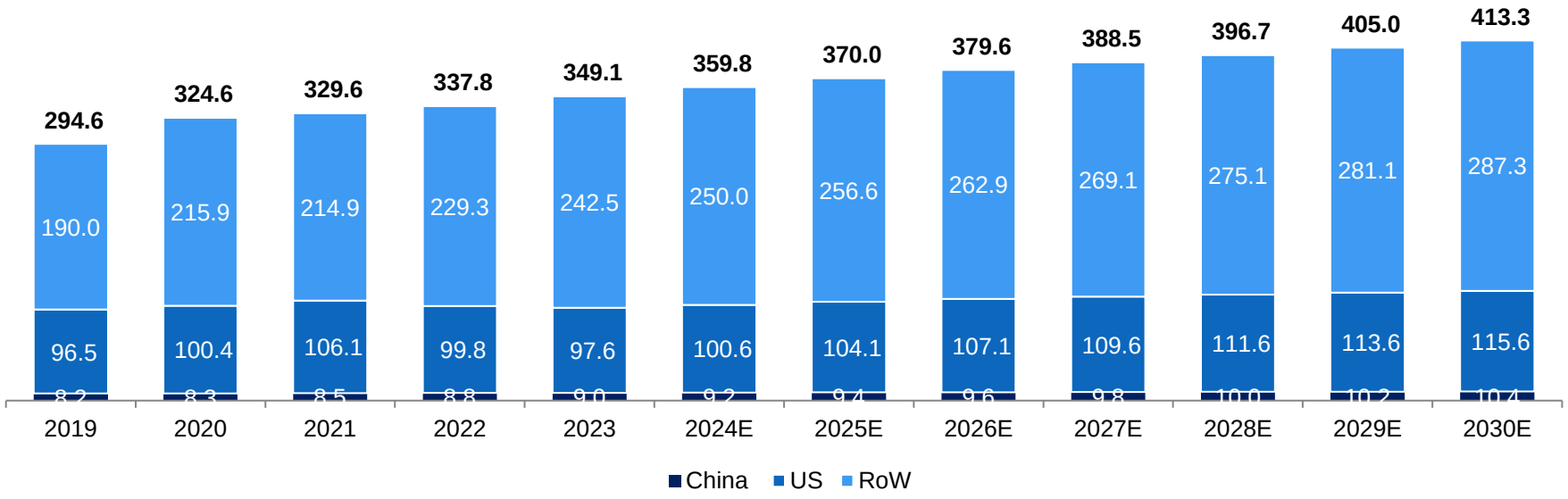


Source: IARC, Frost & Sullivan Analysis

Global Incidence of Melanoma of Skin by Region, 2019-2030E

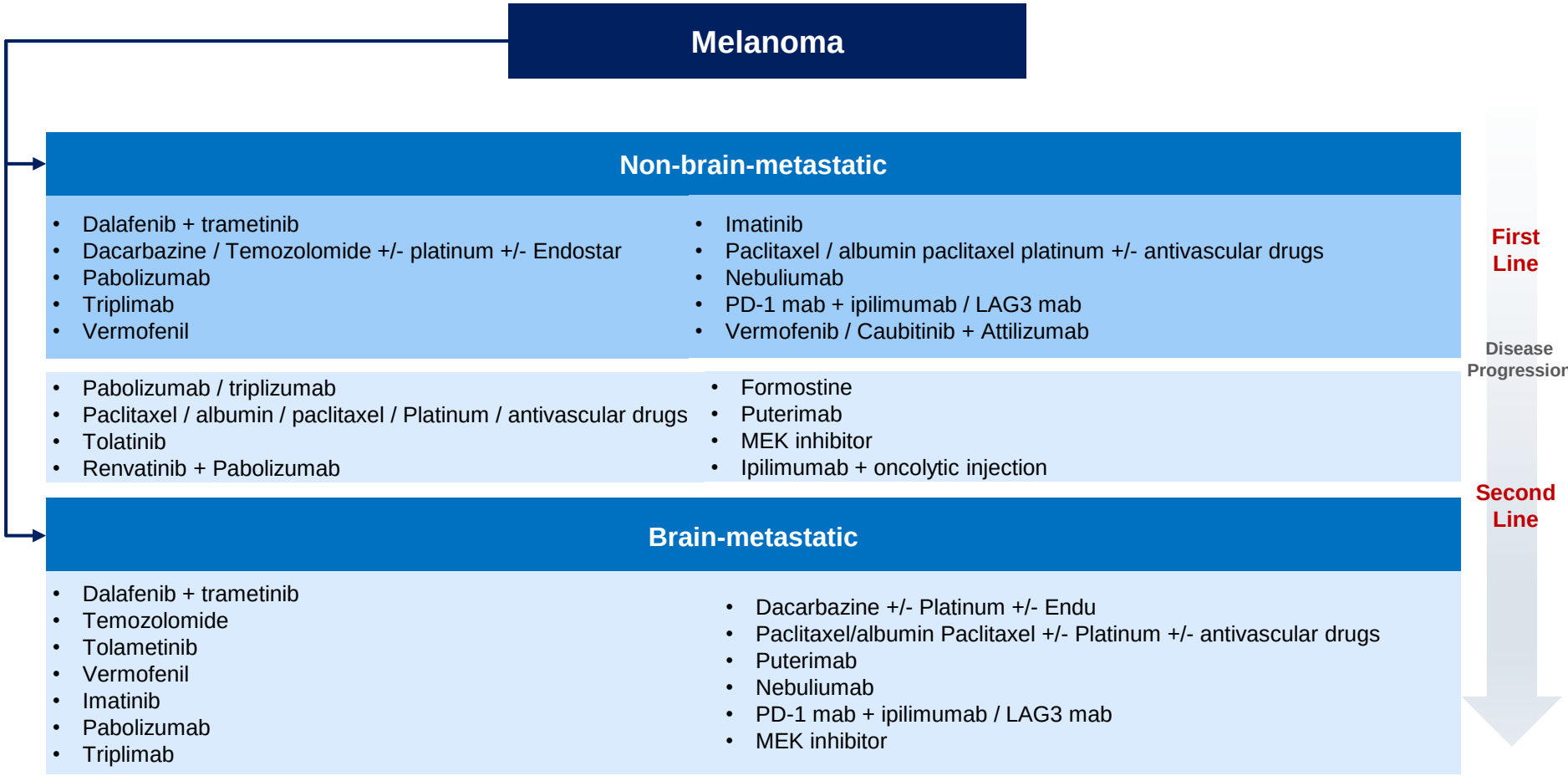
Global Incidence of Melanoma of Skin by Region, 2019-2030E

Period	CAGR			
	China	US	RoW	Total
2019-2023	2.4%	0.3%	6.3%	4.3%
2023-2026E	2.3%	3.1%	2.7%	2.8%
2026E-2030E	2.1%	1.9%	2.2%	2.1%



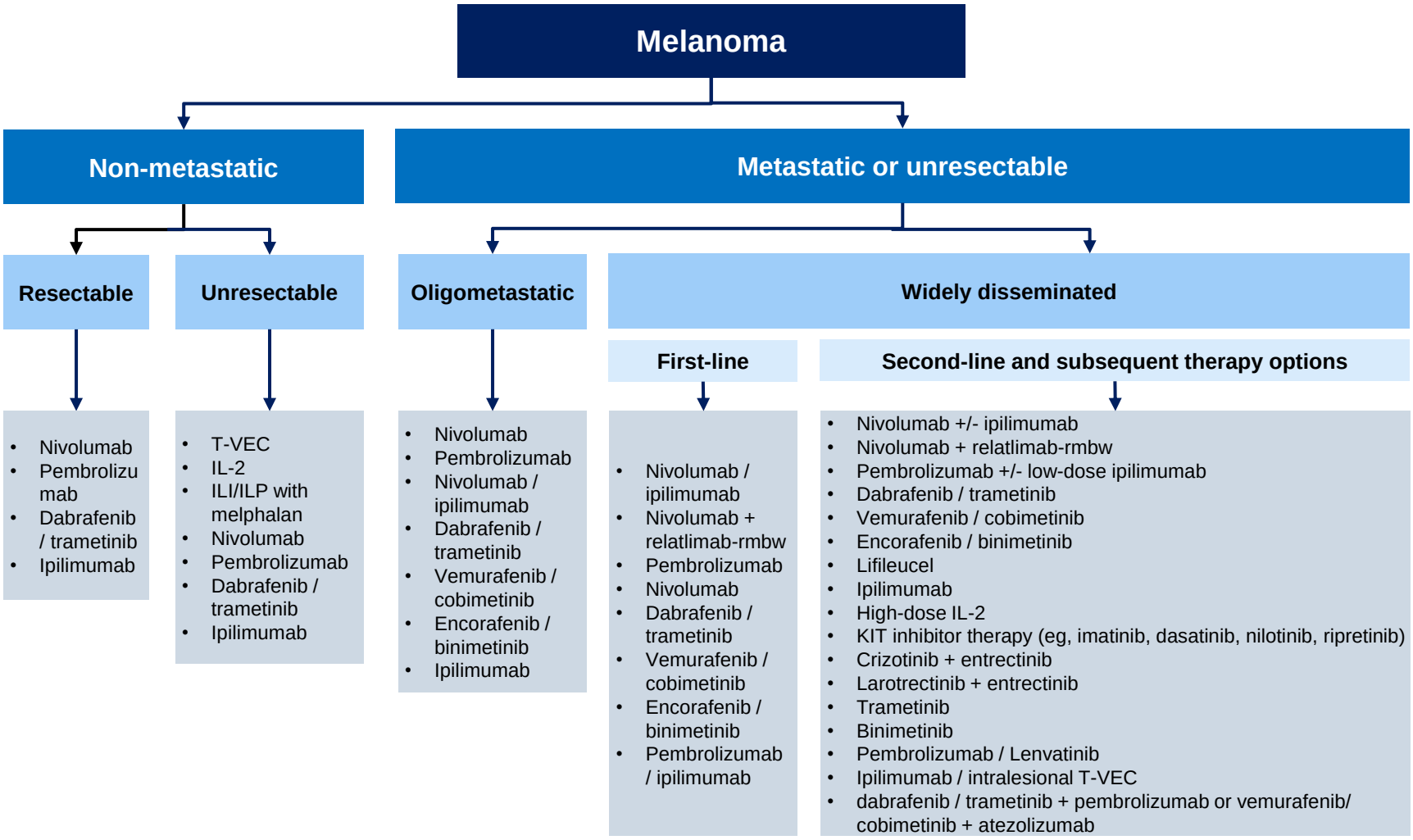
Source: IARC, Frost & Sullivan Analysis

Treatment Paradigm of Melanoma in China



Source: CSCO 2023, Literature Review, Frost & Sullivan Analysis

Treatment Paradigm of Melanoma in the U.S.



Source: NCCN 2024, Literature Review, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Melanoma Approved by NMPA

Drug Name	Brand Name	Target	Company	Indication	Approval Date
Pucotenlimab	普佑恒	PD-1	Lepu Biopharma Co., Ltd.	Melanoma	2022-07-19
Toripalimab	拓益	PD-1	Junshi Biosciences Co.，Ltd	Melanoma	2018-12-17
Pembrolizumab	可瑞达 Keytruda	PD-1	Merck Sharp & Dohme	Melanoma	2018-07-20

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Melanoma Approved by FDA

Drug Name	Brand Name	Target	Company	Indications	Approval Date
NIVOLUMAB + RELATLIMAB	OPDUALAG	LAG3/PD-1	BRISTOL MYERS SQUIBB	Melanoma	2022-03-18
CEMIPLIMAB	LIBTAYO	PD-1	REGENERON PHARMACEUTICALS	Melanoma	2018-09-28
ATEZOLIZUMAB	TECENTRIQ	PD-L1	GENENTECH INC	Melanoma	2016-05-18
NIVOLUMAB	OPDIVO	PD-1	BRISTOL MYERS SQUIBB	Melanoma	2014-12-22
PEMBROLIZUMAB	KEYTRUDA	PD-1	MERCK SHARP DOHME	Melanoma	2014-09-04
IPILIMUMAB	YERVOY	CTLA4	BRISTOL MYERS SQUIBB	Melanoma	2011-03-25

Note: Approval date: First approval date
As of Mya 9th 2025

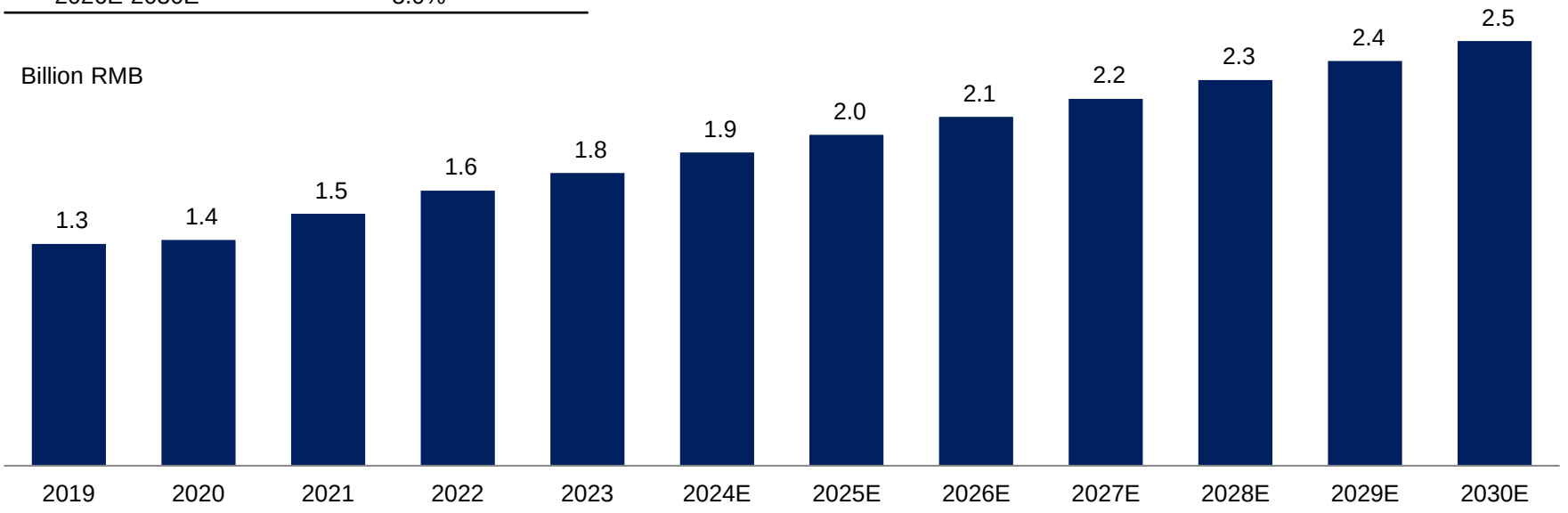
Source: FDA, Frost & Sullivan Analysis

Historical and Forecasted of China Melanoma Drug Market Size, 2019-2030E

- China's melanoma drug market size reached RMB1.8 billion in 2023, with a CAGR of 7.2% from 2019 to 2023. The market size will climb to RMB2.1 billion and RMB2.5 billion in 2026 and 2030 respectively.

Historical and Forecasted of China Melanoma Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	7.2%
2023-2026E	6.0%
2026E-2030E	5.0%



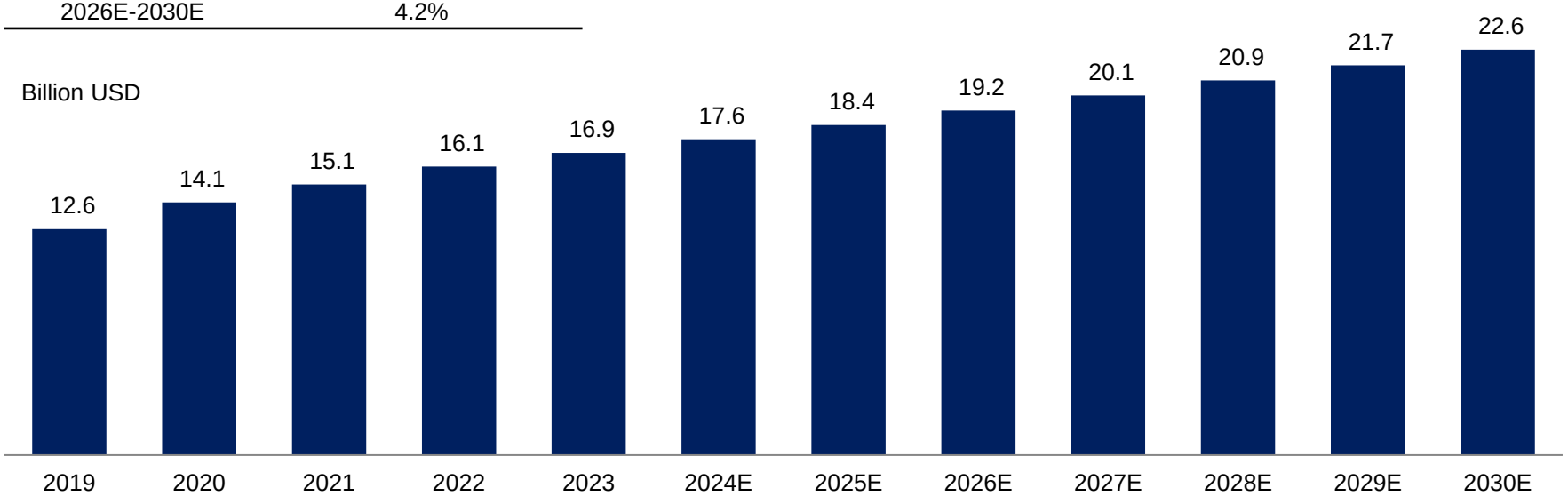
Source: Frost & Sullivan Analysis

Historical and Forecasted of Global Melanoma Drug Market Size, 2019-2030E

- The global melanoma drug market size reached USD16.9 billion in 2023, with a CAGR of 7.5% from 2019 to 2023. The market size is expected to reach USD19.2 billion in 2026, with a CAGR of 4.5% from 2023 to 2026. The market will further grow to USD22.6 billion in 2030, with a CAGR of 4.2% from 2026 to 2030.

Historical and Forecasted of Global Melanoma Drug Market Size, 2019-2030E

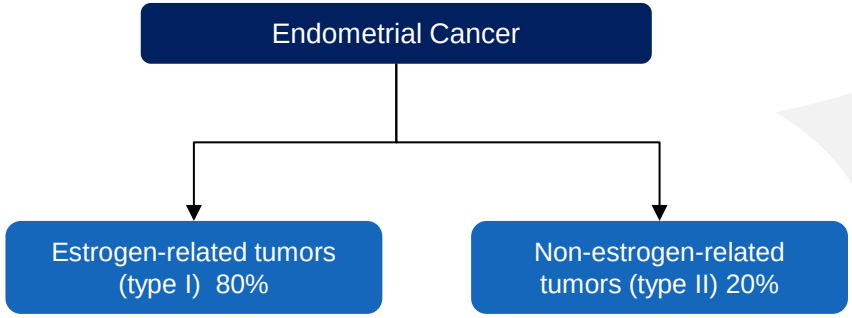
Period	CAGR
2019-2023	7.5%
2023-2026E	4.5%
2026E-2030E	4.2%



Source: Frost & Sullivan Analysis

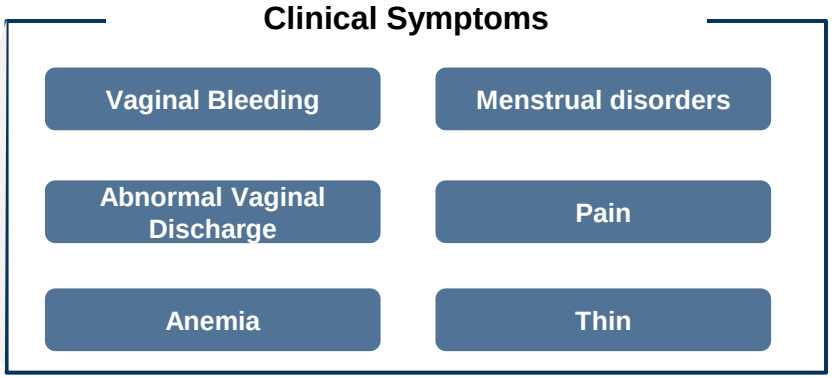
Overview of Endometrial Cancer

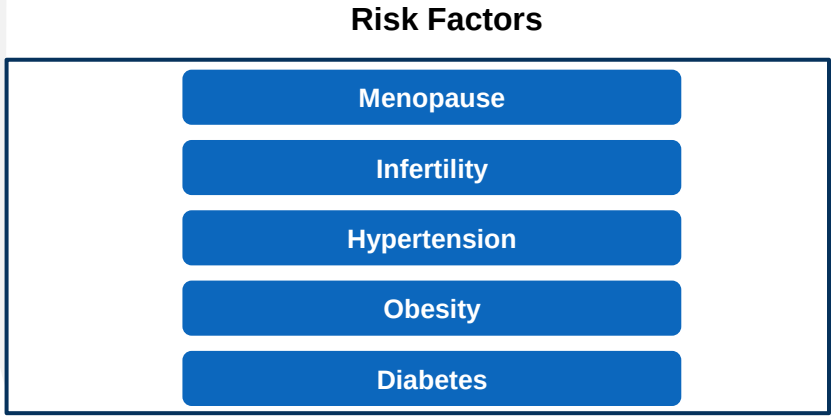
- Endometrial cancer is an epithelial malignant tumor that occurs in the endometrium, also known as uterine corpus cancer. It is one of the top three common malignant tumors of the female reproductive tract and mostly occurs in perimenopausal and postmenopausal women.
- As the average life span increases and lifestyle changes, the incidence of endometrial cancer has continued to rise and the patients have become younger in the past 20 years. In Western countries, endometrial cancer ranks first in the incidence of malignant tumors of the female reproductive system. In China, it is the second most common gynecological malignant tumor after cervical cancer, accounting for about 20% to 30% of gynecological malignant tumors.



The occurrence of type I endometrial cancer is directly related to the continuous stimulation of estrogen. Without progesterone resistance, the endometrium is in a state of excessive proliferation for a long time and further develops into endometrial cancer.

The mechanism of occurrence is still unclear.





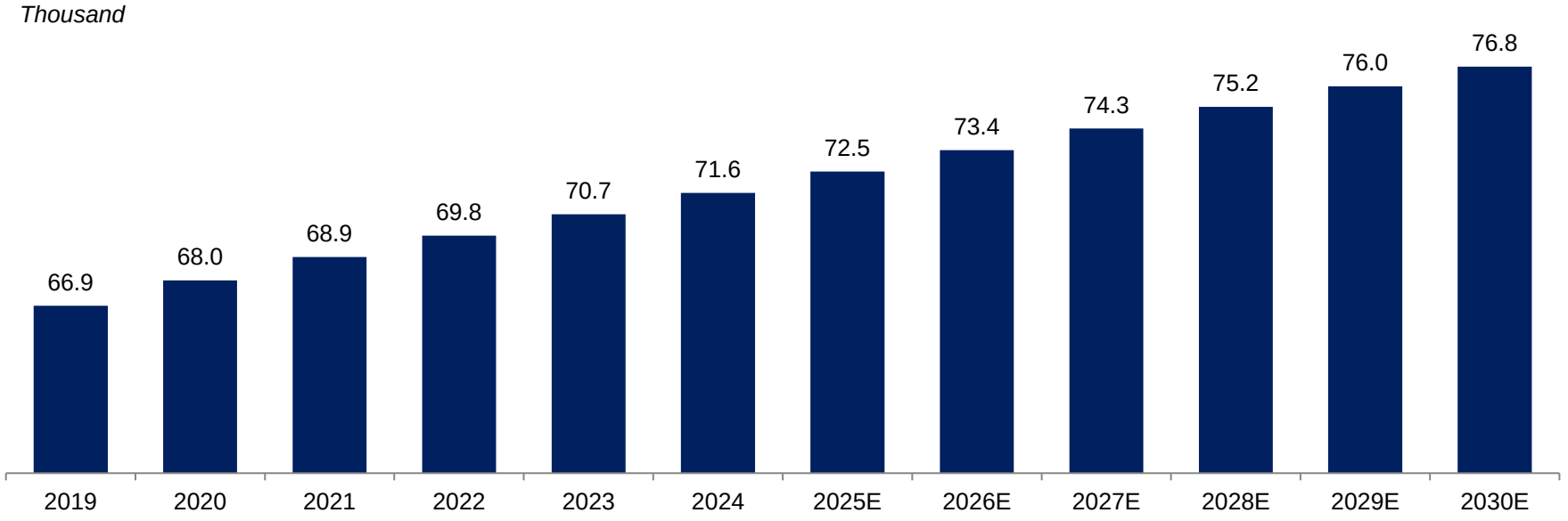
Source: Literature Review, Frost & Sullivan Analysis

Incidence of Endometrial Cancer in China, 2019-2030E

- In China, the number of new endometrial cancer cases rose to 71.6 thousand in 2024, with a compound annual growth rate (CAGR) of 1.4% from 2019. This figure is expected to climb further to 74.3 thousand by 2027, reflecting a CAGR of 1.2% from 2024. Projections indicate that by 2030, the incidence of endometrial cancer could reach 76.8 thousand, at a CAGR of 1.1% from 2027 to 2030.

Incidence of Endometrial Cancer in China, 2019-2030E

Period	CAGR
2019-2024	1.4%
2024-2027E	1.2%
2027E-2030E	1.1%



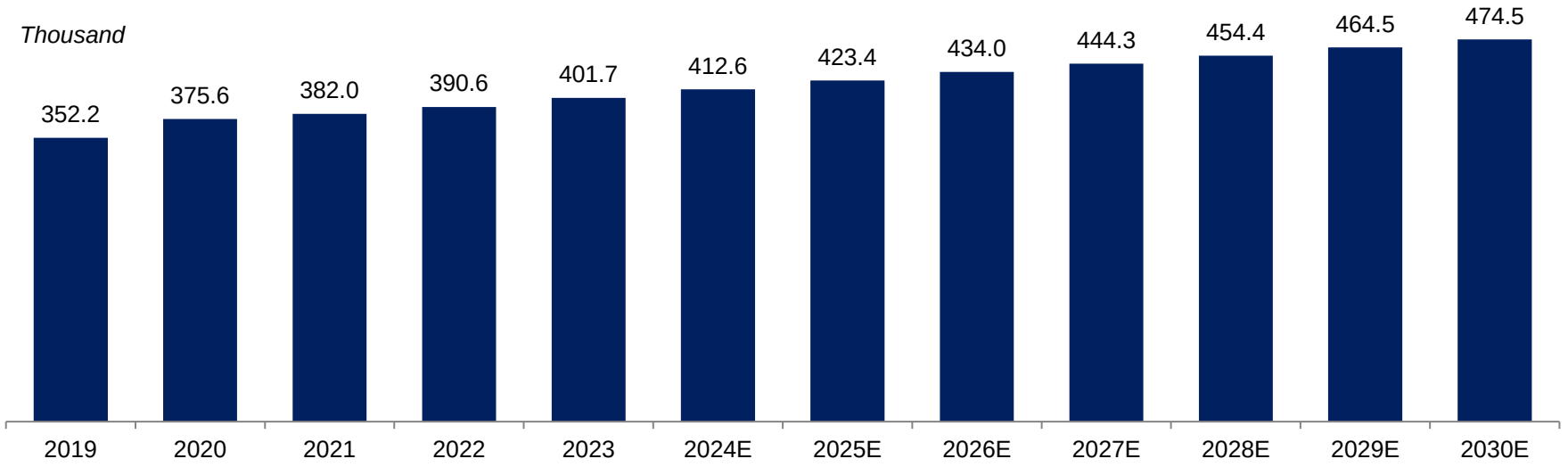
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Endometrial Cancer, 2019-2030E

- Between 2019 and 2023, the global incidence of endometrial cancer increased from 352.2 thousand to 401.7 thousand, showing a CAGR of 3.3%. Projections suggest that this number will continue to rise to 434.0 thousand by 2026, at a CAGR of 2.6% from 2023 to 2026. By 2030, it is expected to reach 474.5 thousand, at a CAGR of 2.3%.

Global Incidence of Endometrial Cancer, 2019-2030E

Period	CAGR
2019-2023	3.3%
2023-2026E	2.6%
2026E-2030E	2.3%

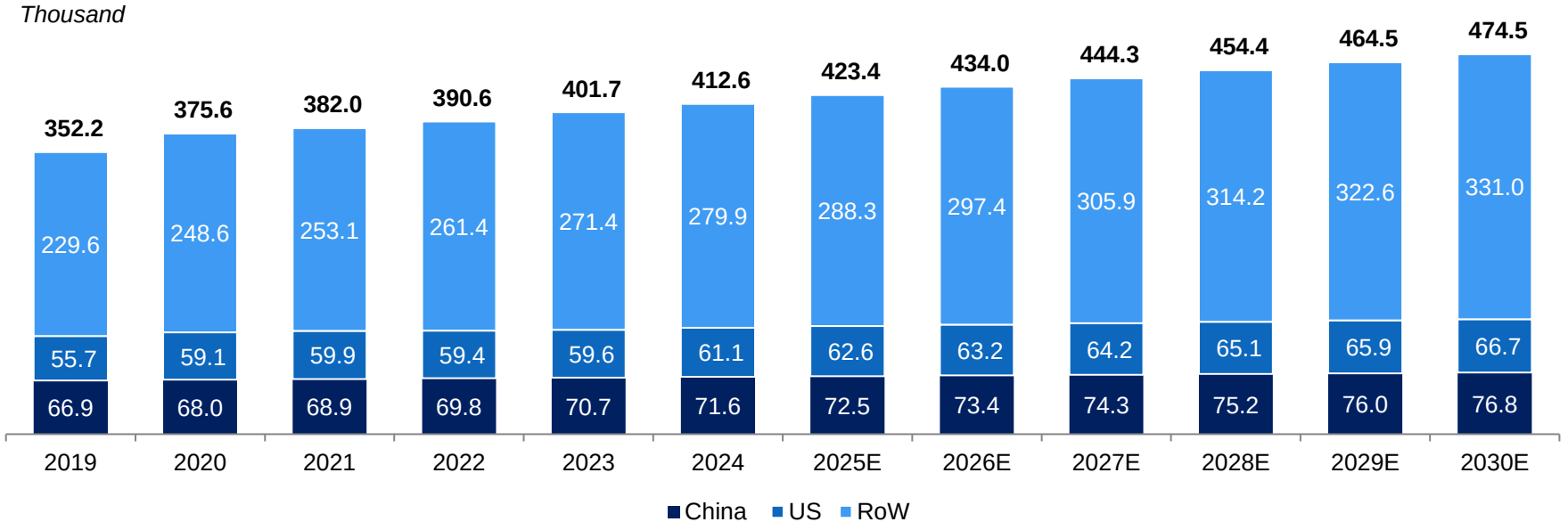


Source: IARC, Frost & Sullivan Analysis

Global Incidence of Endometrial Cancer by Region, 2019-2030E

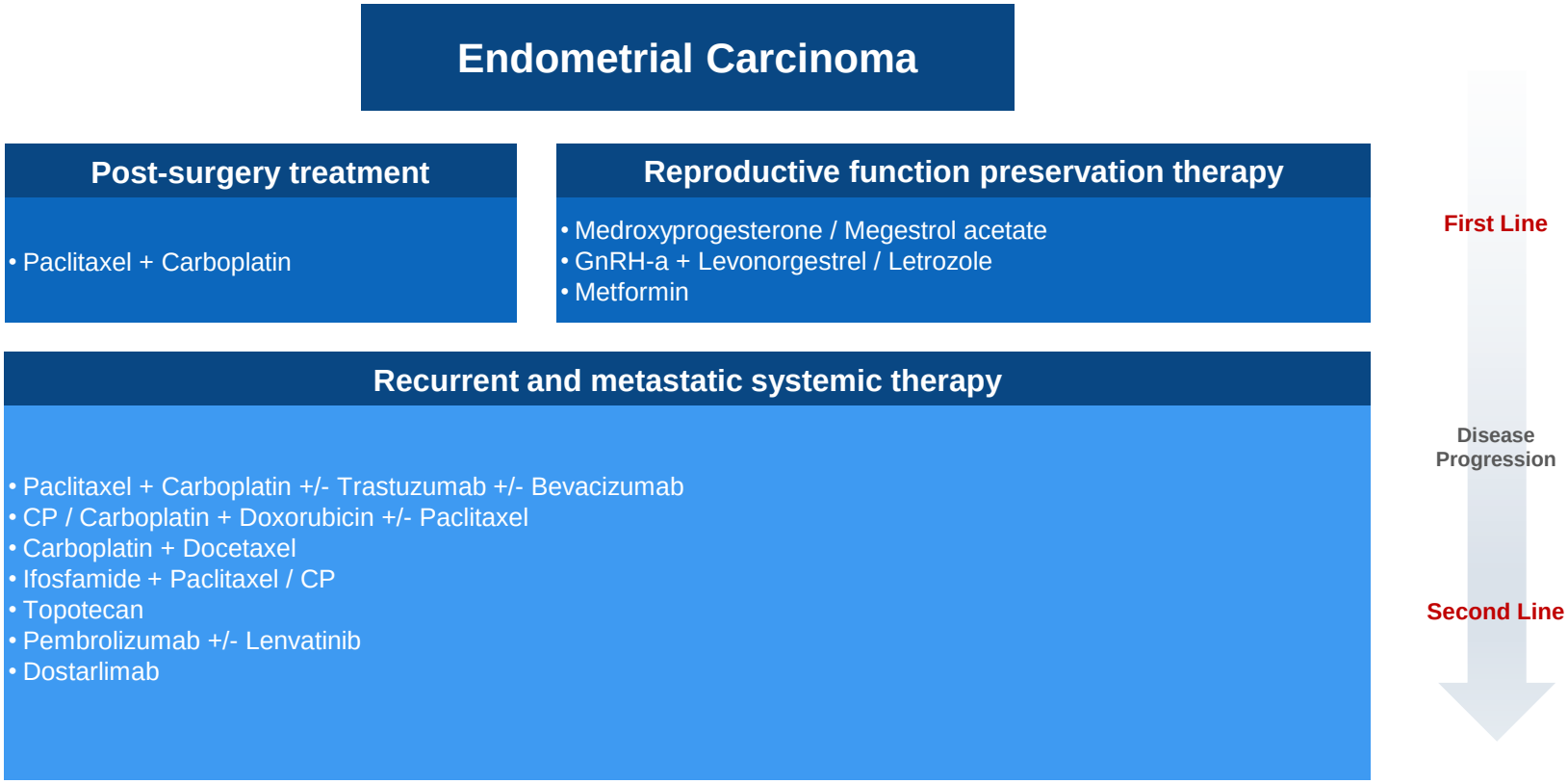
Global Incidence of Endometrial Cancer by Region, 2019-2030E

Period	CAGR			
	China	US	RoW	Total
2019-2024	1.4%	1.9%	4.0%	3.2%
2024-2030E	1.2%	1.5%	2.8%	2.4%



Source: IARC, Frost & Sullivan Analysis

Treatment Paradigm of Endometrial Carcinoma in China



Notes: RT=Radiation therapy; CP = cisplatin; X = capecitabine; 5-FU = 5-Fluorouracil; G = gemcitabine

Source: CSCO2023, Literature Review, Frost & Sullivan Analysis

Treatment Paradigm of Endometrial Carcinoma in the U.S.

Systemic Therapy for Endometrial Carcinoma

Primary or Adjuvant Therapy (Stage I–IV)

First Line

- Chemoradiation Therapy
  - CP + RT followed by carboplatin / paclitaxel
  - X /mitomycin
  - G
  - Paclitaxel

Systemic Therapy

- Carboplatin / paclitaxel / pembrolizumab / dostarlimab-gxly (for stage III–IV tumors)
- Carboplatin / paclitaxel / trastuzumab (for stage III/IV HER2-positive uterine serous carcinoma)

Recurrent Disease

Disease Progression

- Carboplatin / paclitaxel / pembrolizumab / dostarlimab-gxly / docetaxel / bevacizumab
- Lenvatinib / pembrolizumab
- Pembrolizumab
- Dostarlimab-gxly

Second Line

- CP / doxorubicin / paclitaxel
- Carboplatin
- Liposomal doxorubicin
- Paclitaxel
- Topotecan
- Bevacizumab
- Temsirolimus
- Cabozantinib
- Docetaxel
- Ifosfamide / paclitaxel / CP

- Lenvatinib / pembrolizumab
- Dostarlimab-gxly
- Avelumab
- Nivolumab
- Fam-trastuzumab deruxtecan-nxki
- Larotrectinib
- Entrectinib

Hormonal Therapy for Uterine-Limited Disease

- Levonorgestrel IUD
- Megestrol acetate
- Medroxyprogesterone acetate

Hormonal Therapy for Recurrent or Metastatic Endometrial Carcinoma

- Megestrol acetate / tamoxifen
- Everolimus / letrozole
- Medroxyprogesterone acetate / tamoxifen
- Medroxyprogesterone acetate
- Megestrol acetate
- Aromatase inhibitors
- Tamoxifen
- Fulvestrant

Notes: RT=Radiation therapy; CP = cisplatin; X = capecitabine; 5-FU = 5-Fluorouracil; G = gemcitabine

Source: NCCN2024, Literature Review, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Endometrial Cancer Approved by NMPA

Drug Name	Brand Name	Target	Company	Indication	Approval Date
Bevacizumab	安维汀 Avastin	VEGF	Roche	SCLC	2010-02-26
Pembrolizumab	可瑞达 Keytruda	PD-1	Merck Sharp & Dohme	Melanoma	2018-07-20

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Endometrial Cancer Approved by FDA

Drug Name	Brand Name	Target	Company	Indications	Approval Date
DOSTARLIMAB	JEMPERLI	PD-1	GLAXOSMITHKLINE	Endometrial Cancer	2021-04-22
PEMBROLIZUMAB	KEYTRUDA	PD-1	MERCK SHARP DOHME	Endometrial Cancer	2014-09-04
BEVACIZUMAB	AVASTIN	VEGF	ROCHE	Endometrial Cancer	2004-02-26

Note: Approval date: First approval date
As of Mya 9th 2025

Source: FDA, Frost & Sullivan Analysis

Overview of Multiple Myeloma

- Multiple Myeloma (MM) is a cancer of the plasma cells in the bone marrow. Plasma cells are antibody-producing white blood cells that are critical to the immune system. Myeloma begins when healthy plasma cells become cancerous and grow out of control. MM often results in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures.
- Multiple myeloma can be subdivided into hyperdiploid MM (h-MM) and non-hyperdiploid MM (nh-MM) based on their aneuploidy status, and the two subtypes have different prognosis and survival outcomes. Patients with hyperdiploid multiple myeloma tend to have a better prognosis than those with non-hyperdiploid subtype.

Subtypes of Multiple Myeloma

hyperdiploid (h-MM)	non-hyperdiploid (nh-MM)
• Characterized by trisomies • More indolent form of disease • Tendency toward more favorable outcome • Slightly more common among males • More common in the elderly • Higher incidence of MM bone disease	• Encompasses hypodiploid, pseudopiploid, and near tetraploid MM • More aggressive form of the disease with a worse prognosis • Prevalent among younger patients • Can be further divided into subtypes based on genetic translocation

Bone pain | ***Low blood counts*** | ***High blood levels of calcium*** | ***Nervous system symptoms***

Symptoms of MM

Risk Factors

- Increasing Age
- Sex
- Race
- Family History
- Workplace exposures
- Obesity
- Other plasma cell diseases

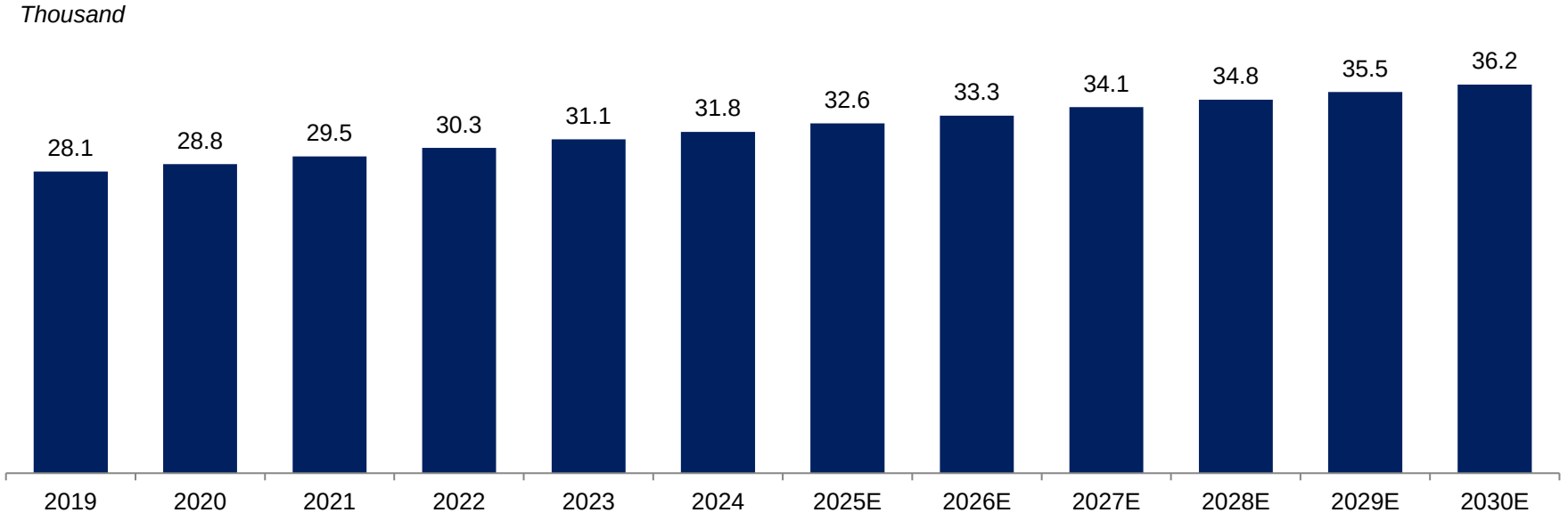
Source: American Cancer Society, International Myeloma Foundation, Frost & Sullivan Analysis

Incidence of Multiple Myeloma in China, 2019-2030E

- In China, the number of new multiple myeloma cases rose to 31.8 thousand in 2024, with a compound annual growth rate (CAGR) of 2.5% from 2019. This figure is expected to climb further to 34.1 thousand by 2027, reflecting a CAGR of 2.4% from 2024. Projections indicate that by 2030, the incidence of multiple myeloma could reach 36.2 thousand, at a CAGR of 2.0% from 2027 to 2030.

Incidence of Multiple Myeloma in China, 2019-2030E

Period	CAGR
2019-2024	2.5%
2024-2027E	2.4%
2027E-2030E	2.0%



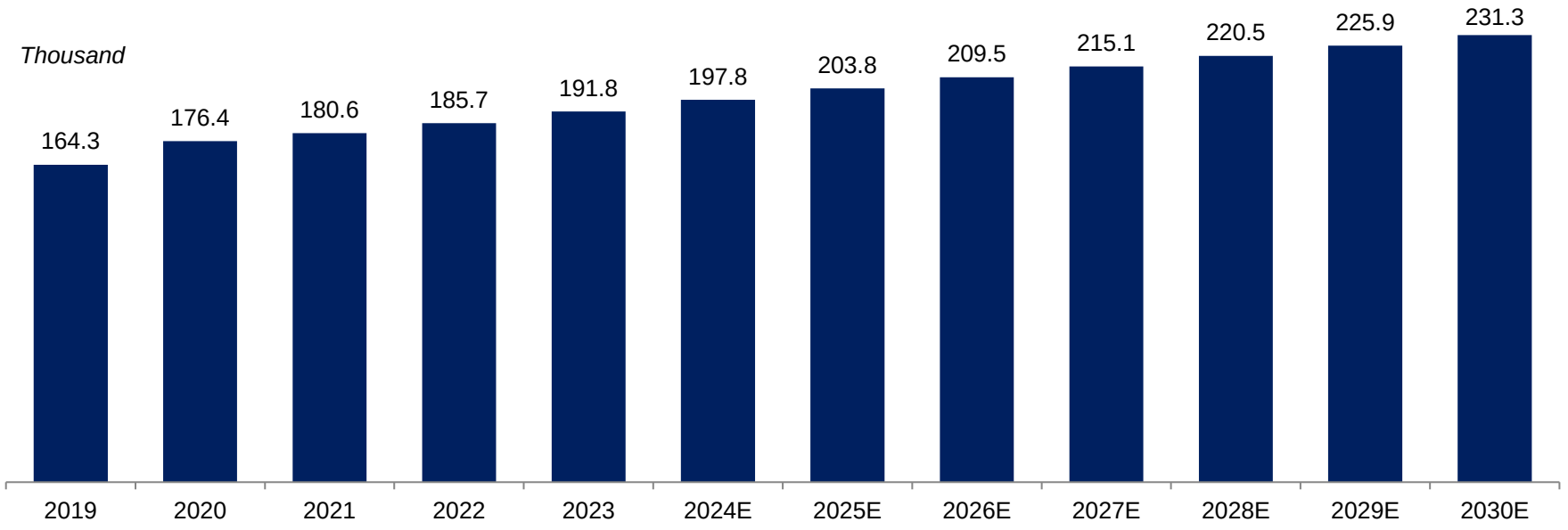
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Multiple Myeloma, 2019-2030E

- Between 2019 and 2023, the global incidence of multiple myeloma increased from 164.3 thousand to 191.8 thousand, showing a CAGR of 3.9%. Projections suggest that this number will continue to rise to 209.5 thousand by 2026, at a CAGR of 3.0% from 2023 to 2026. By 2030, it is expected to reach 231.3 thousand, at a CAGR of 2.5%.

Global Incidence of Multiple Myeloma, 2019-2030E

Period	CAGR
2019-2023	3.9%
2023-2026E	3.0%
2026E-2030E	2.5%

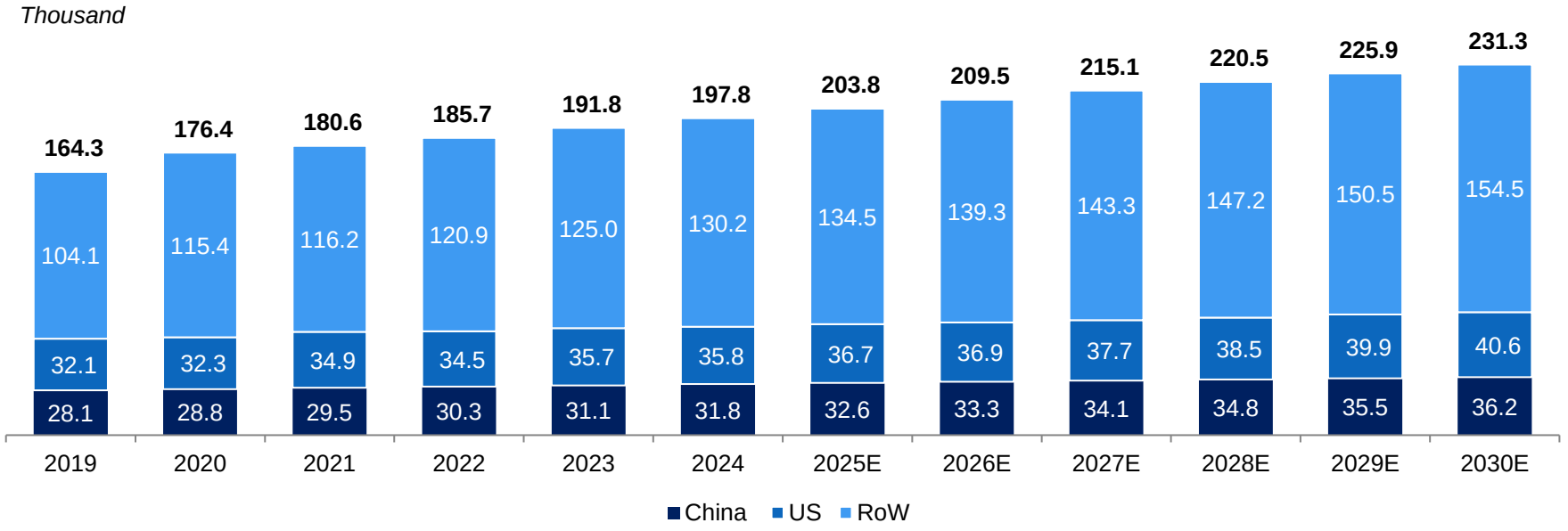


Source: IARC, Frost & Sullivan Analysis

Global Incidence of Multiple Myeloma by Region, 2019-2030E

Global Incidence of Multiple Myeloma by Region, 2019-2030E

Period	CAGR			
	China	US	RoW	Total
2019-2024	2.6%	2.2%	4.6%	3.8%
2024-2030E	2.1%	2.1%	2.9%	2.6%

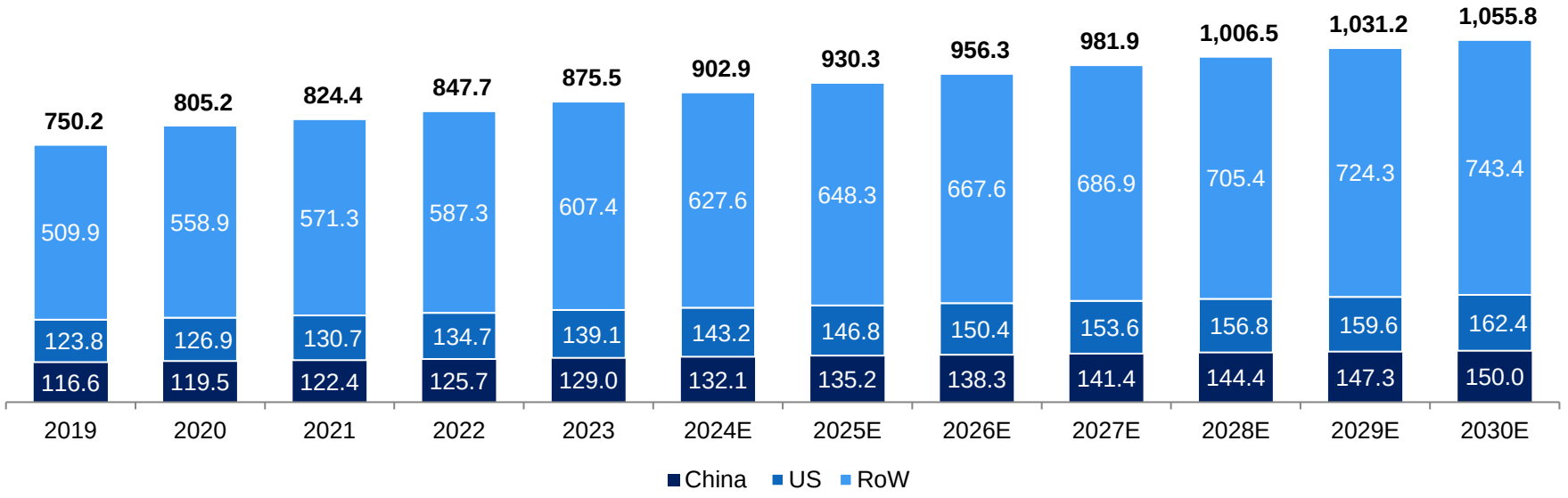


Source: IARC, Frost & Sullivan Analysis

Global Prevalence of Multiple Myeloma by Region, 2019-2030E

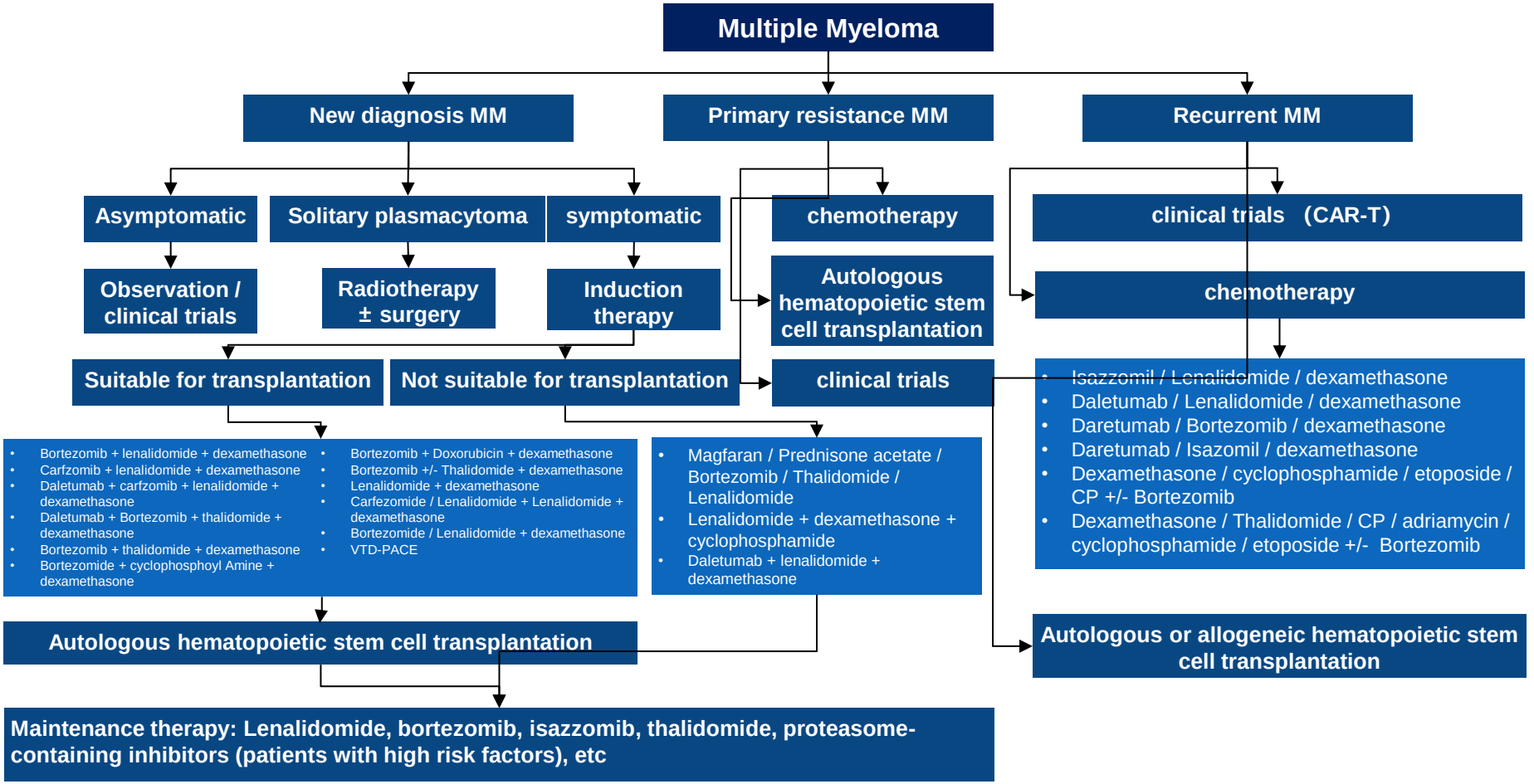
Global Prevalence of Multiple Myeloma by Region, 2019-2030E

Period	CAGR			
	China	US	RoW	Total
2019-2023	2.6%	3.0%	4.5%	3.9%
2023-2026E	2.3%	2.6%	3.2%	3.0%
2026E-2030E	2.1%	1.9%	2.7%	2.5%



Source: IARC, Frost & Sullivan Analysis

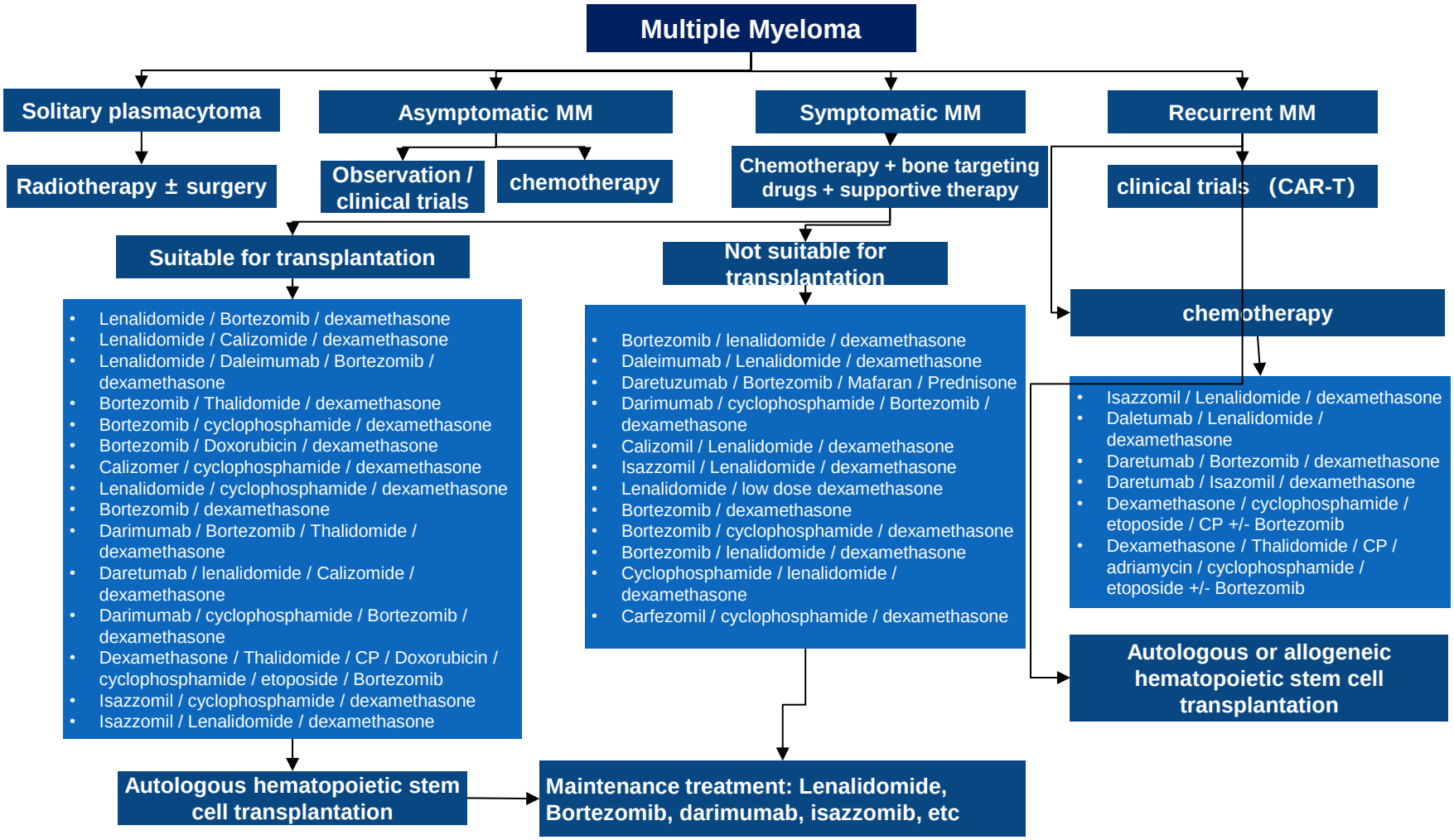
Treatment Paradigm of Multiple Myeloma in China



Notes: RT=Radiation therapy; CP = cisplatin; X = capecitabine; 5-FU = 5-Fluorouracil; G = gemcitabine; VTD-PACE= Bortezomib + dexamethasone thalidomide + Cisplatin + Doxorubicin + cyclophosphamide + etopoxib

Source: CSCO2023, Literature Review, Frost & Sullivan Analysis

Treatment Paradigm of Multiple Myeloma in the U.S.



Notes: RT=Radiation therapy; CP = cisplatin; X = capecitabine; 5-FU = 5-Fluorouracil; G = gemcitabine; VTD-PACE= Bortezomib + dexamethasone thalidomide + Cisplatin + Doxorubicin + cyclophosphamide + etopoxib

Source: NCCN2024, Literature Review, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Multiple Myeloma Approved by NMPA

Drug Name	Brand Name	Target	Company	Indication	Approval Date
Elranatamab	ELREXFIO	BCMA , CD3	Pfizer	Multiple Myeloma	2025-03-04
Talquetamab	拓立珂 TALVEY	CD3 , GPRC5D	Janssen Pharmaceutica	Multiple Myeloma	2025-02-08
Isatuximab	赛可益 SARCLISA	CD38	Sanofi	Multiple Myeloma	2025-01-08
Teclistamab	泰立珂 TECVAYLI	BCMA , CD3	Janssen Pharmaceutica	Multiple Myeloma	2024-06-18
Daratumumab	兆珂 DARZALEX	CD38	Janssen Pharmaceutica	Multiple Myeloma	2019-07-04
Denosumab	安加维 XGEVA	RANKL	Amgen	Multiple Myeloma	2019-05-21

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Multiple Myeloma Approved by FDA

Drug Name	Brand Name	Target	Company	Indications	Approval Date
ELRANATAMAB	ELREXFIO	BCMA/CD3	PFIZER	Multiple Myeloma	2023-08-14
TALQUETAMAB-TGVS	TALVEY	CD3/GPRC5D	JANSSEN BIOTECH	Multiple Myeloma	2023-08-09
TECLISTAMAB-CQYV	TECVAYLI	BCMA/CD3	JANSSEN BIOTECH	Multiple Myeloma	2022-10-25
ISATUXIMAB-IRFC	SARCLISA	CD38	SANOFI AVENTIS	Multiple Myeloma	2020-03-02
ELOTUZUMAB	EMPLICITI	SLAMF7	BRISTOL MYERS SQUIBB	Multiple Myeloma	2015-11-30
DARATUMUMAB	DARZALEX	CD38	JANSSEN BIOTECH	Multiple Myeloma	2015-11-16
DENOSUMAB	XGEVA	RANKL	AMGEN	Multiple Myeloma	2010-06-01

Note: Approval date: First approval date
As of Mya 9th 2025

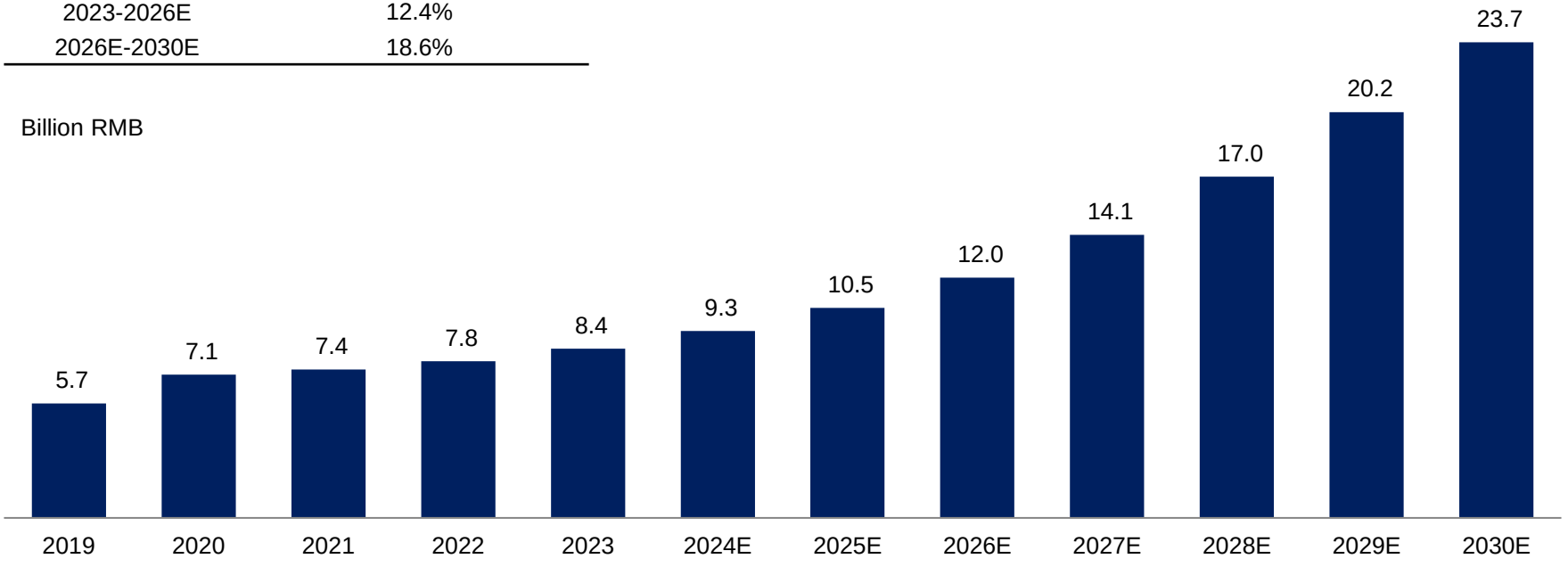
Source: FDA, Frost & Sullivan Analysis

Historical and Forecasted of China Multiple Myeloma Drug Market Size, 2019-2030E

- China's multiple myeloma drug market size reached RMB8.4 billion in 2023, with a CAGR of 10.3% from 2019 to 2023. The market size will climb to RMB12.0 billion and RMB23.7 billion in 2026 and 2030 respectively.

Historical and Forecasted of China Multiple Myeloma Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	10.3%
2023-2026E	12.4%
2026E-2030E	18.6%



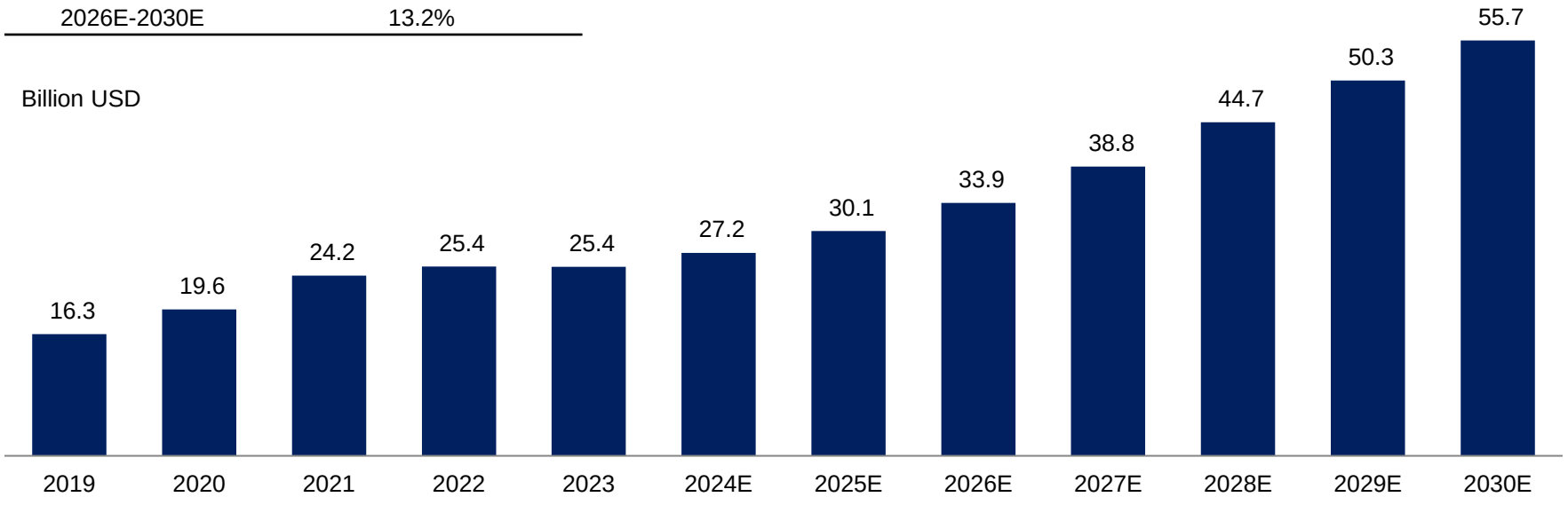
Source: Frost & Sullivan Analysis

Historical and Forecasted of Global Multiple Myeloma Drug Market Size, 2019-2030E

- The global multiple myeloma drug market size reached USD25.4 billion in 2023, with a CAGR of 11.6% from 2019 to 2023. The market size is expected to reach USD33.9 billion in 2026, with a CAGR of 10.2% from 2023 to 2026. The market will further grow to USD55.7 billion in 2030, with a CAGR of 13.2% from 2026 to 2030.

Historical and Forecasted of Global Multiple Myeloma Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	11.6%
2023-2026E	10.2%
2026E-2030E	13.2%



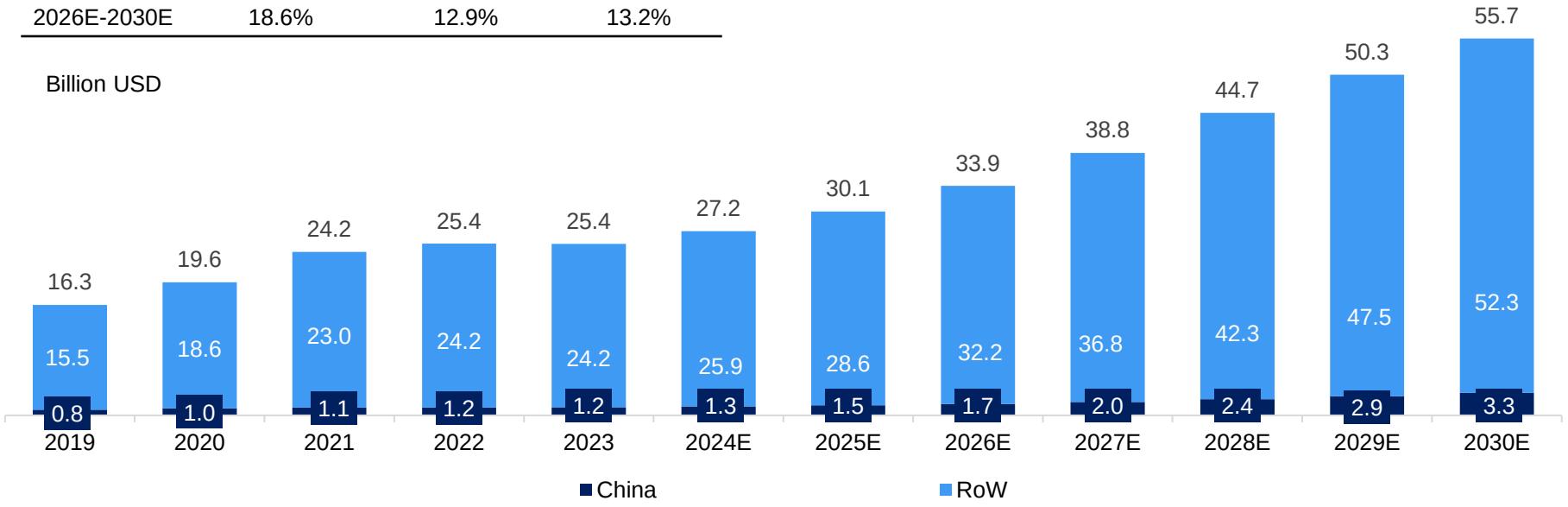
Source: Frost & Sullivan Analysis

Historical and Forecasted of Global Multiple Myeloma Drug Market Size, 2019-2030E

- The size of global multiple myeloma drug market was USD 25.4 billion in 2023, and is expected to reach USD 33.9 billion and USD 55.7 billion in 2026 and 2030 respectively, representing a CAGR of 10.2% from 2023 to 2026 and 13.2% from 2026 to 2030. The size of China multiple myeloma drug market was USD 1.2 billion in 2023, and is expected to reach USD 1.7 billion and USD 3.3 billion in 2026 and 2030 respectively, representing a CAGR of 12.4% from 2023 to 2026 and 18.6% from 2026 to 2030.

Historical and Forecasted of Global Multiple Myeloma Drug Market Size, 2019-2030E

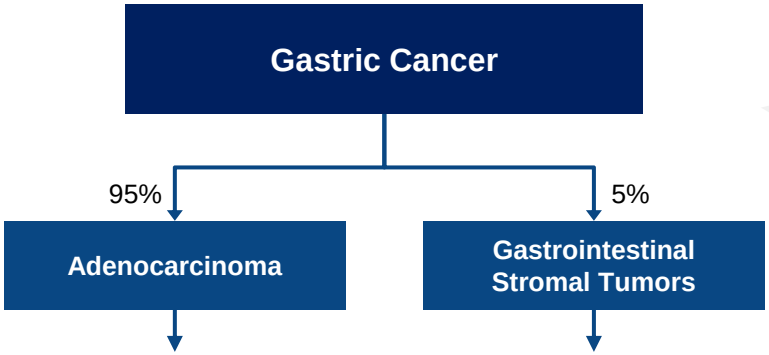
CAGR	China	RoW	Total
2019-2023	9.6%	11.7%	11.6%
2023-2026E	12.4%	10.1%	10.2%
2026E-2030E	18.6%	12.9%	13.2%



Source: Frost & Sullivan Analysis

Overview of Gastric Cancer

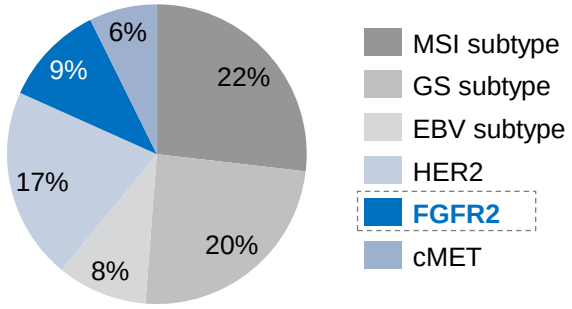
- Gastric cancer is a type of tumor developing from the lining of the stomach. The cancer may spread from the stomach to other parts of the body, particularly the liver, lungs, bones, lining of the abdomen and lymph nodes. Most of the time, stomach cancer develops in stages over years.
- Early symptoms may include heartburn, upper abdominal pain, nausea and loss of appetite. Later signs and symptoms may include weight loss, yellowing of the skin, etc.



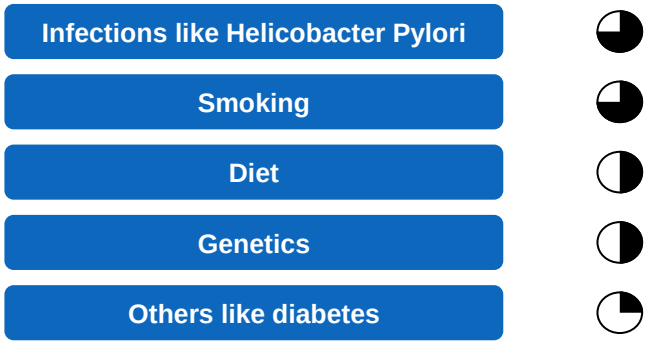
- Most cancers of the gastric cancer are adenocarcinomas. A stomach cancer or gastric cancer almost always is an adenocarcinoma. These cancers develop from the cells that form the innermost lining of the stomach (the mucosa).

- Gastrointestinal stromal tumors are the most common mesenchymal neoplasms of the gastrointestinal tract. GISTs arise in the smooth muscle pacemaker interstitial cell of Cajal, or similar cells.

GC Mutation Alterations



Risk Factors



● The most relevant factor ○ The least relevant factor

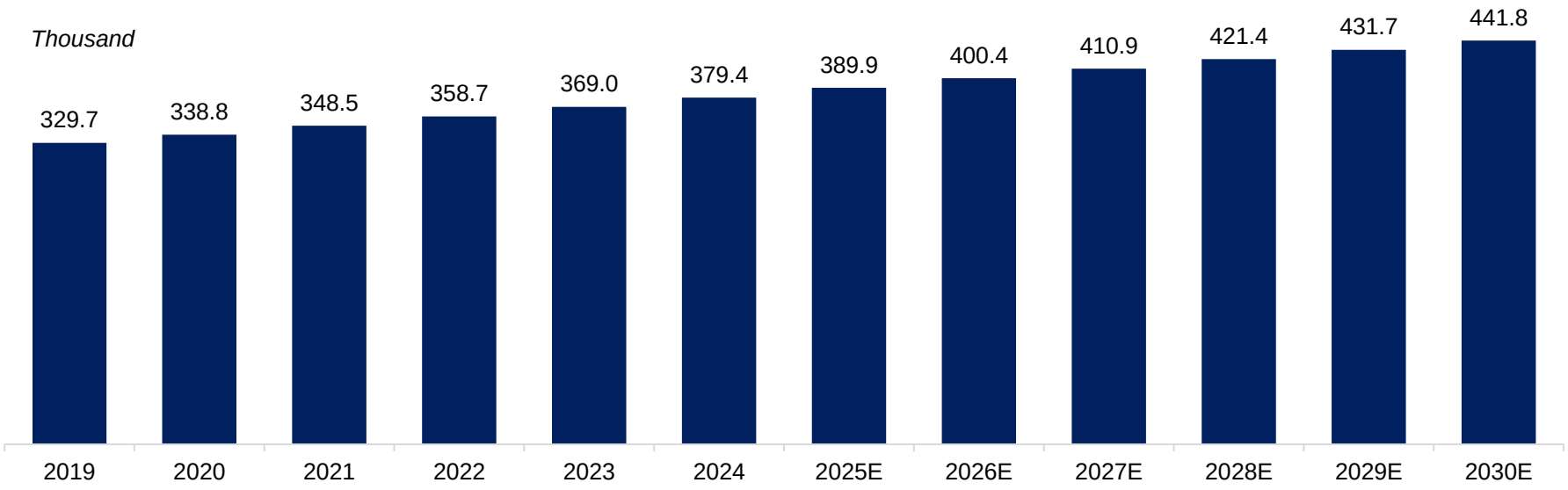
Source: Literature Review, Frost & Sullivan Analysis

Incidence of Gastric Cancer in China, 2019-2030E

- Incidence number of gastric cancer in China increased from 329.7 thousand to 379.4 thousand in 2019 and 2024. The number is expected to grow to 410.9 thousand in 2027 at a CAGR of 2.7% from 2024 to 2027. The number is expected to grow to 441.8 thousand in 2030, at a CAGR of 2.4%.

Incidence of Gastric Cancer in China, 2019-2030E

Period	CAGR
2019-2024	2.8%
2024-2027E	2.7%
2027E-2030E	2.4%



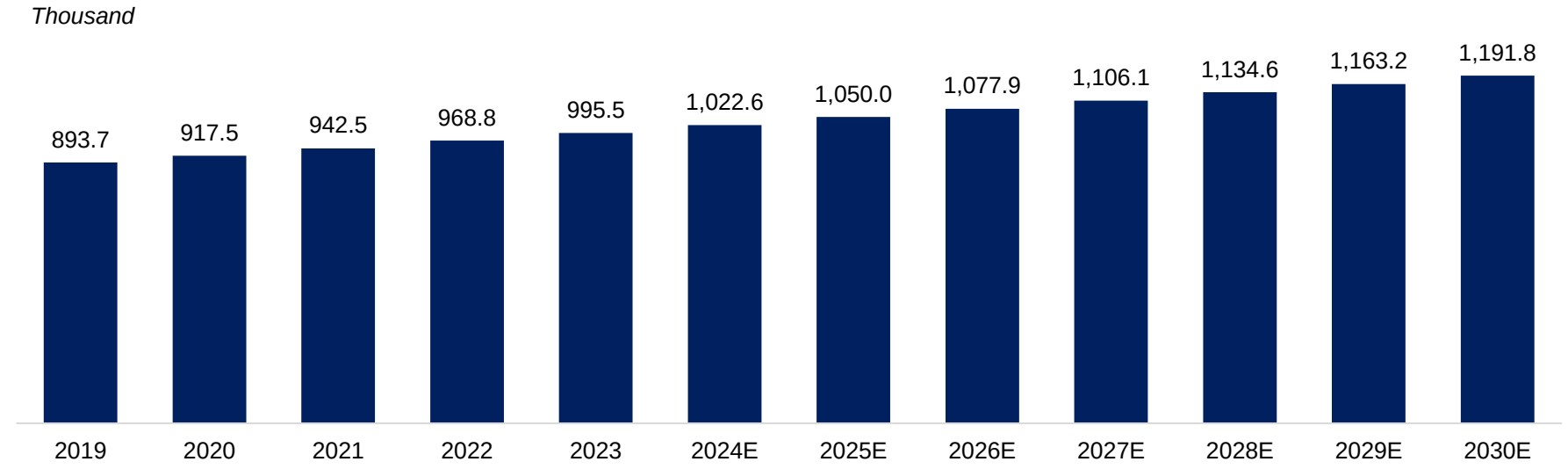
Source: NCCR, Frost & Sullivan Analysis

Global Incidence of Gastric Cancer, 2019-2030E

- Incidence number of gastric cancer around the world increased from 893.7 thousand to 995.5 thousand in 2019 and 2023. The number is expected to grow to 1,077.9 thousand in 2026 at a CAGR of 2.7% from 2023 to 2026. The number is expected to grow to 1,191.8 thousand in 2030, at a CAGR of 2.5%.

Global Incidence of Gastric Cancer, 2019-2030E

Period	CAGR
2019-2023	2.7%
2023-2026E	2.7%
2026E-2030E	2.5%



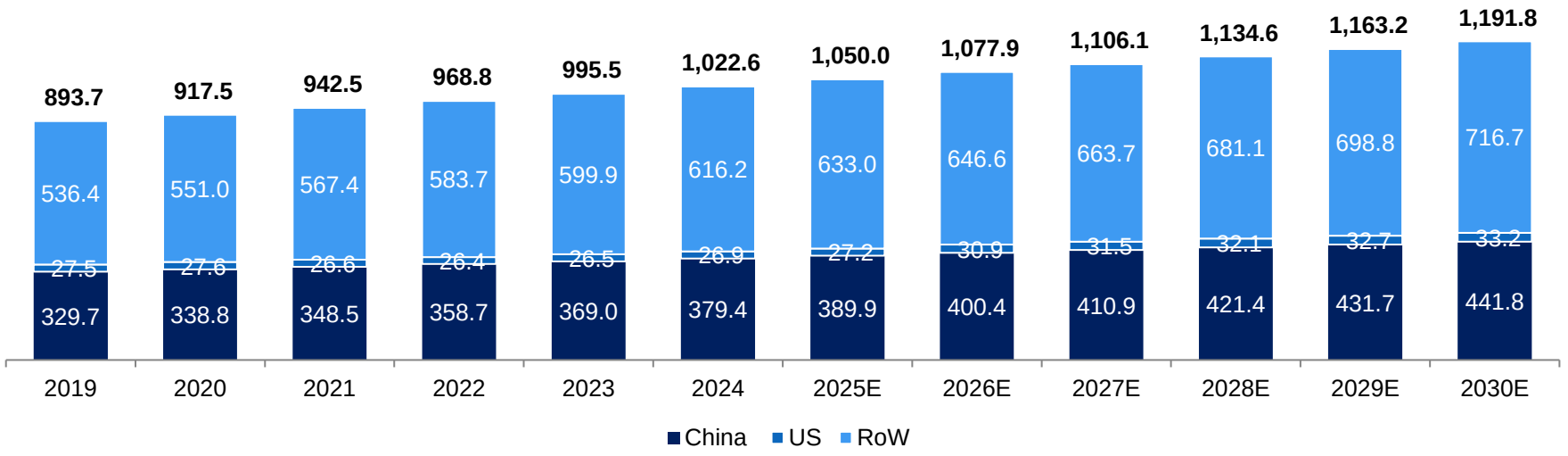
Source: IARC, Frost & Sullivan Analysis

Global Incidence of Gastric Cancer by Region, 2019-2030E

Global Incidence of Gastric Cancer by Region, 2019-2030E

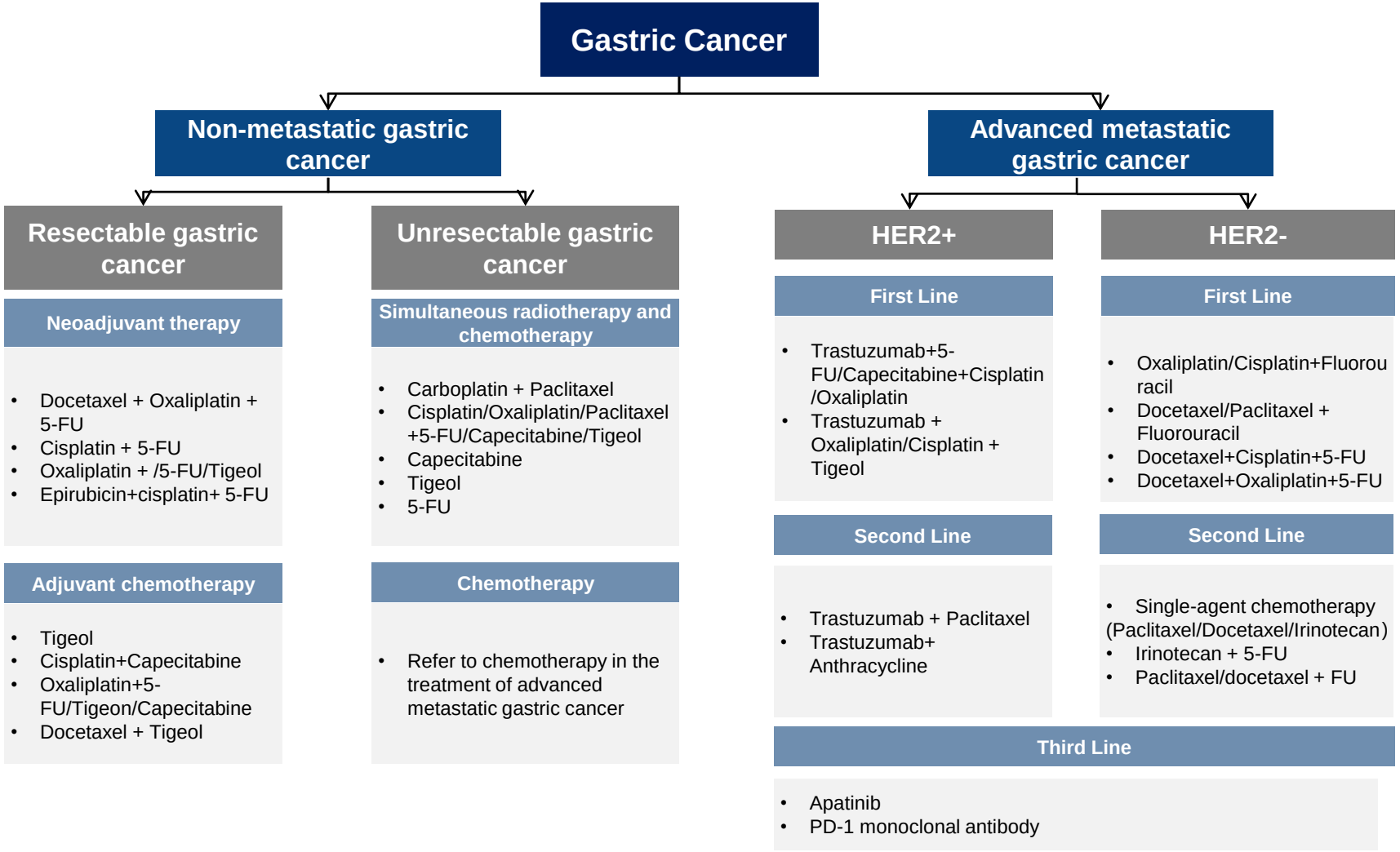
Period	CAGR			
	China	US	RoW	Total
2019-2024	2.8%	-0.5%	2.8%	2.7%
2024-2030E	2.6%	3.6%	2.6%	2.6%

Thousand



Source: IARC, Frost & Sullivan Analysis

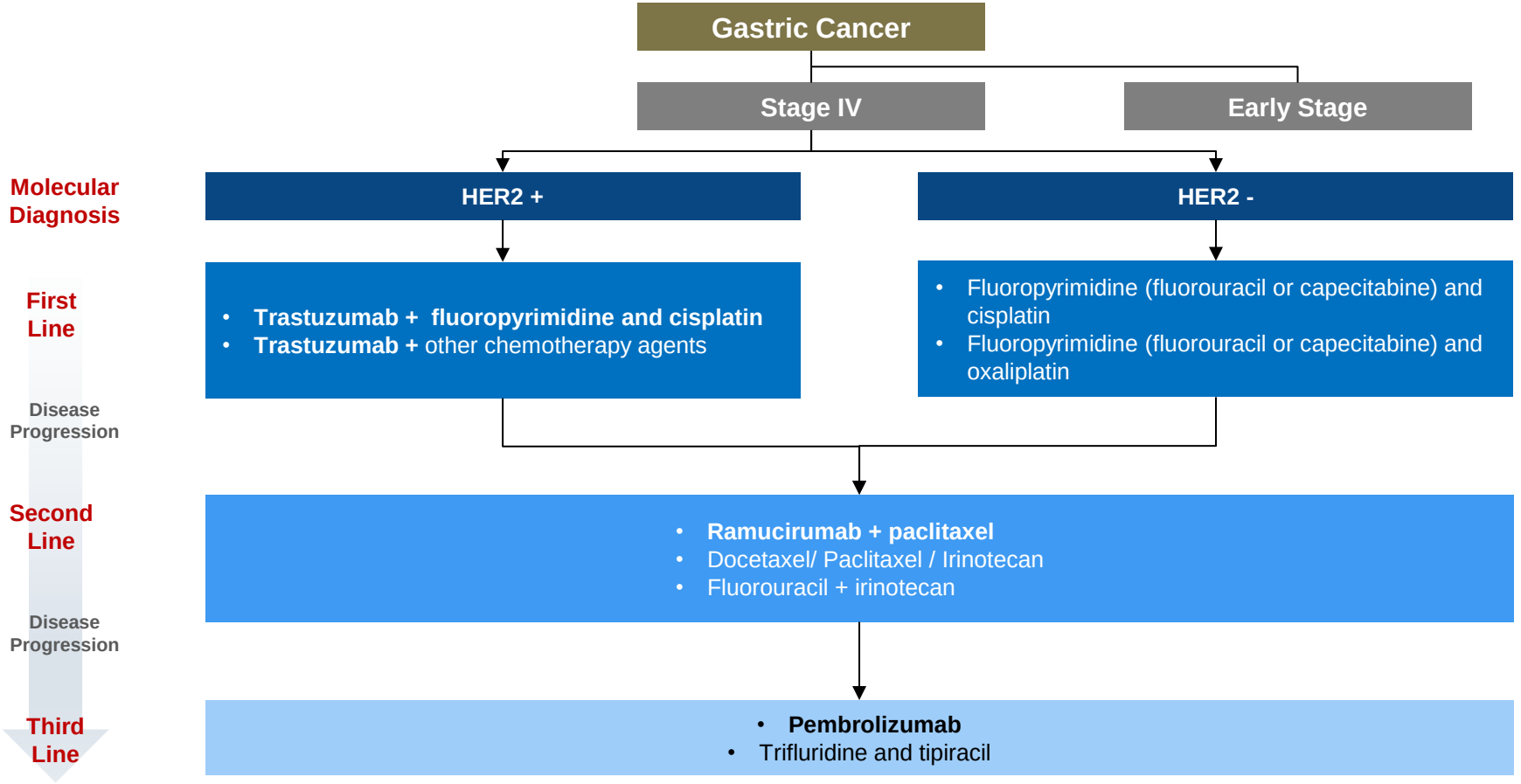
Treatment Paradigm for Gastric Cancer in China



Source: CSCO, Frost & Sullivan Analysis

Treatment Paradigm for Gastric Cancer in the U.S.

- Surgery is the main method in treating gastric cancer of stage I-III. However, if the cancer deteriorates to stage IV, the treatment switches to precision oncology therapies in combination with chemotherapies to alleviate symptoms and improve the patients' life quality. Therapies for HER2 negative patients' treatment are still limited.



Source: NCCN, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Gastric Cancer Approved by NMPA

Drug Name	Brand Name	Target	Company	Indication	Approval Date
Zolbetuximab	威络益	CLDN-18.2	Astellas Pharma Europe B.V.	G/GEJ Cancer	2024-12-25
Serplulimab	汉斯状	PD-1	Henlius Biopharmaceutical Co.,LTD	G/GEJ Cancer	2022-03-22
Ramucirumab	希冉择 Cyramza	VEGFR2	Eli Lilly	G/GEJ Cancer	2022-03-16
Sugemalimab	择捷美	PD-L1	Pfizer	G/GEJ Cancer	2021-12-20
Disitamab vedotin	爱地希	HER2	Remegen Co.,Ltd.	G/GEJ Cancer	2021-06-08
Tislelizumab	百泽安	PD-1	Boehringer Ingelheim / BeiGene	G/GEJ Cancer	2019-12-26
Sintilimab	达伯舒	PD-1	Innovent Biologics Co., Ltd.	G/GEJ Cancer	2018-12-24
Pembrolizumab	可瑞达 Keytruda	PD-1	Merck Sharp & Dohme	G/GEJ Cancer	2018-07-20
Nivolumab	欧狄沃 OPDIVO	PD-1	Bristol Myers Squibb	G/GEJ Cancer	2018-06-15

Note: Approval date: First approval date
As of Mya 9th 2025

Source: NMPA, Frost & Sullivan Analysis

Competitive Landscape of Antibody Drug on Gastric Cancer Approved by FDA

Drug Name	Brand Name	Target	Company	Indications	Approval Date
TISLELIZUMAB-JSGR	TEVIMBRA	PD-1	BEIGENE	G/GEJ Cancer	2024-12-26
ZOLBETUXIMAB-CLZB	VYLOY	CLDN-18.2	ASTELLAS	G/GEJ Cancer	2024-10-18
NIVOLUMAB	OPDIVO	PD-1	BRISTOL MYERS SQUIBB	G/GEJ Cancer	2014-12-22
PEMBROLIZUMAB	KEYTRUDA	PD-1	MERCK SHARP DOHME	G/GEJ Cancer	2014-09-04
RAMUCIRUMAB	CYRAMZA	VEGFR2	ELI LILLY AND CO	G/GEJ Cancer	2014-04-21
TRASTUZUMAB	HERCEPTIN	HER2	GENENTECH	G/GEJ Cancer	1998-09-25

Note: Approval date: First approval date
As of Mya 9th 2025

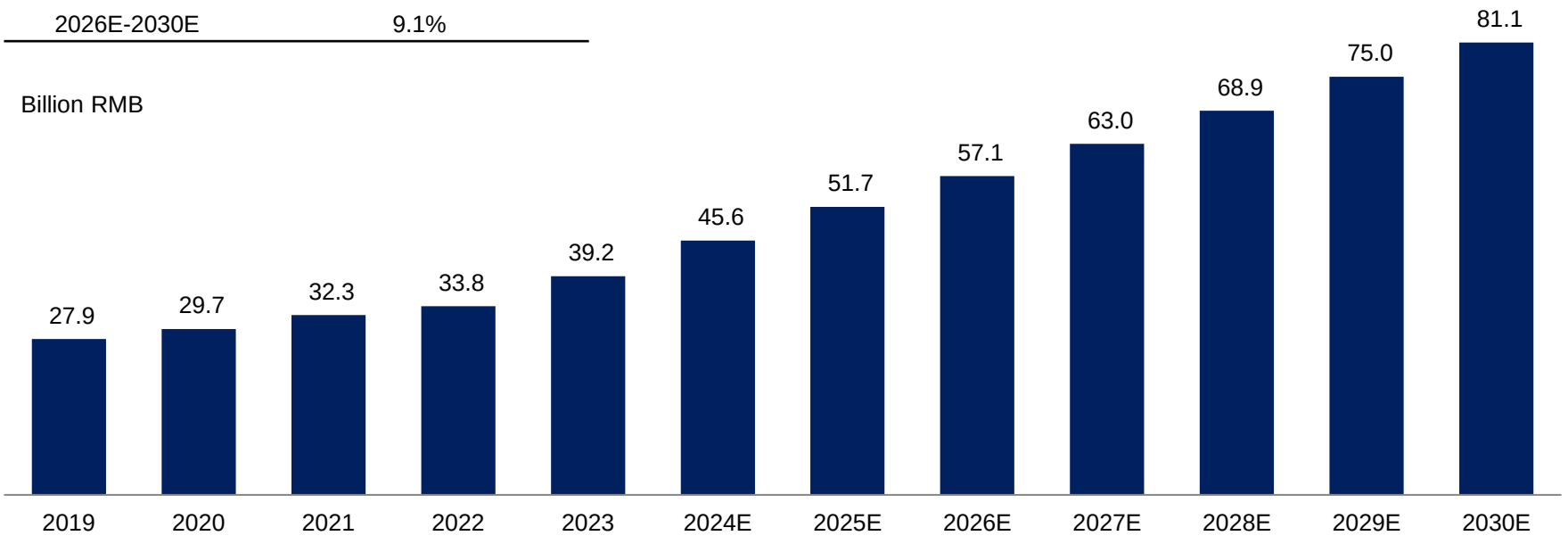
Source: FDA, Frost & Sullivan Analysis

Historical and Forecasted of China Gastric Cancer Drug Market Size, 2019-2030E

- China's G/GEJ cancer drug market size reached RMB39.2 billion in 2023, with a CAGR of 8.8% from 2019 to 2023. The market size will climb to RMB57.1 billion and RMB81.1 billion in 2026 and 2030 respectively.

Historical and Forecasted of China Gastric Cancer Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	8.8%
2023-2026E	13.4%
2026E-2030E	9.1%



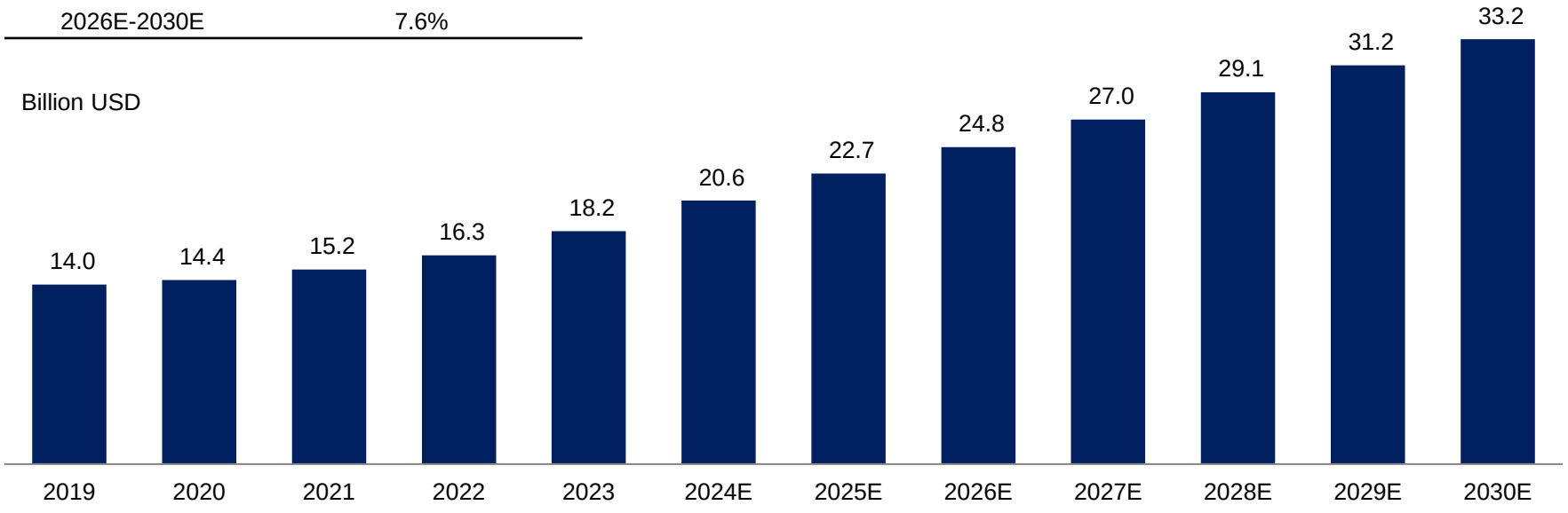
Source: Frost & Sullivan Analysis

Historical and Forecasted of Global Gastric Cancer Drug Market Size, 2019-2030E

- The global G/GEJ cancer drug market size reached USD18.2 billion in 2023, with a CAGR of 6.7% from 2019 to 2023. The market size is expected to reach USD24.8 billion in 2026, with a CAGR of 10.8% from 2023 to 2026. The market will further grow to USD33.2 billion in 2030, with a CAGR of 7.6% from 2026 to 2030.

Historical and Forecasted of Global Gastric Cancer Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	6.7%
2023-2026E	10.8%
2026E-2030E	7.6%



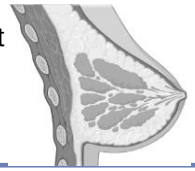
Source: Frost & Sullivan Analysis

Overview of Breast Cancer

- Breast cancer is a malignant tumor that occurs in the epithelial tissue of the breast. It is the most common malignant tumor in women and occasionally in men. Developing from breast tissue, breast cancer may present as a lump in the breast, a change in breast shape, dimpling of the skin, fluid coming from the nipple, a newly inverted nipple, or a red or scaly patch of skin. The incidence of breast cancer is related to high endogenous estrogen levels in patients, endometriosis, menstrual fertility factors, genetic factors, environmental and lifestyle factors, etc., and the incidence peaks around the age of 50. Treatment measures should be based on histological classification, TNM staging and molecular classification of breast cancer.

Definition

- Breast cancer is cancer that develops from breast tissue. Worldwide, breast cancer is the leading type of cancer in women, but is occasionally occurring in men.



Molecular classification

		ER	PR	HER2-	Ki-67
Luminal	Luminal A	+	+ (High expression)	-	Low
	Luminal B (HER2-)	+	- Or low expression	-	High
	Luminal B (HER2+)	+	any	+	any
Erb-B2 expression		-	-	+	/
Basal-like		-	-	-	/

Source: Literature Review, Frost & Sullivan analysis

Histological classification

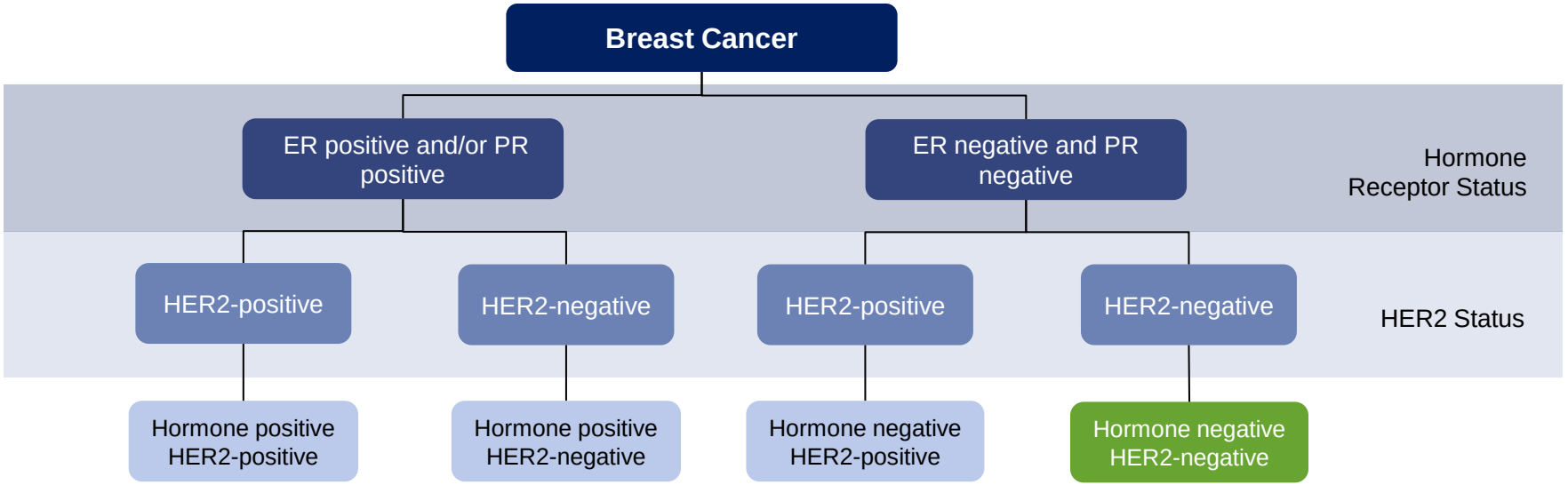
non-invasive carcinoma	Carcinoma in situ means that the lesion is limited to the primary site without metastasis, including ductal carcinoma in situ and lobular carcinoma in situ
invasive carcinoma	Cancer cells infiltrate and invade surrounding tissues extensively, occurring metastasis
Others	Rare and accounting for a small proportion

Risk Factors

- Genetic predisposition (BRCA1 or BRCA2 mutations)
- Estrogen and progesterone exposure
- Oral contraceptives or birth control drugs
- Atypical hyperplasia of the breast
- Lobular carcinoma in situ
- Lifestyle factors (weight, food, alcohol, physical activity)
- Breast density (dense breast tissue)
- Family history of breast cancer

Classification of Breast Cancer

- Breast cancer classification divides breast cancer into categories according to different gene expression and receptor status.
- Among all different kinds of receptors in breast cancer cells, three most important classification being: estrogen receptor (ER), progesterone receptor (PR), and HER2.
- Either a test called an immunohistochemistry (IHC) test or fluorescence in situ hybridization (FISH) test is used to find out if cancer cells have a high level of the HER2 protein. About 20% of breast tumors have higher levels of a protein known as HER2. These cancers are called HER2-positive breast cancers, otherwise called HER2-negative breast cancer (HER2-negative breast cancer includes HER2 low expression).



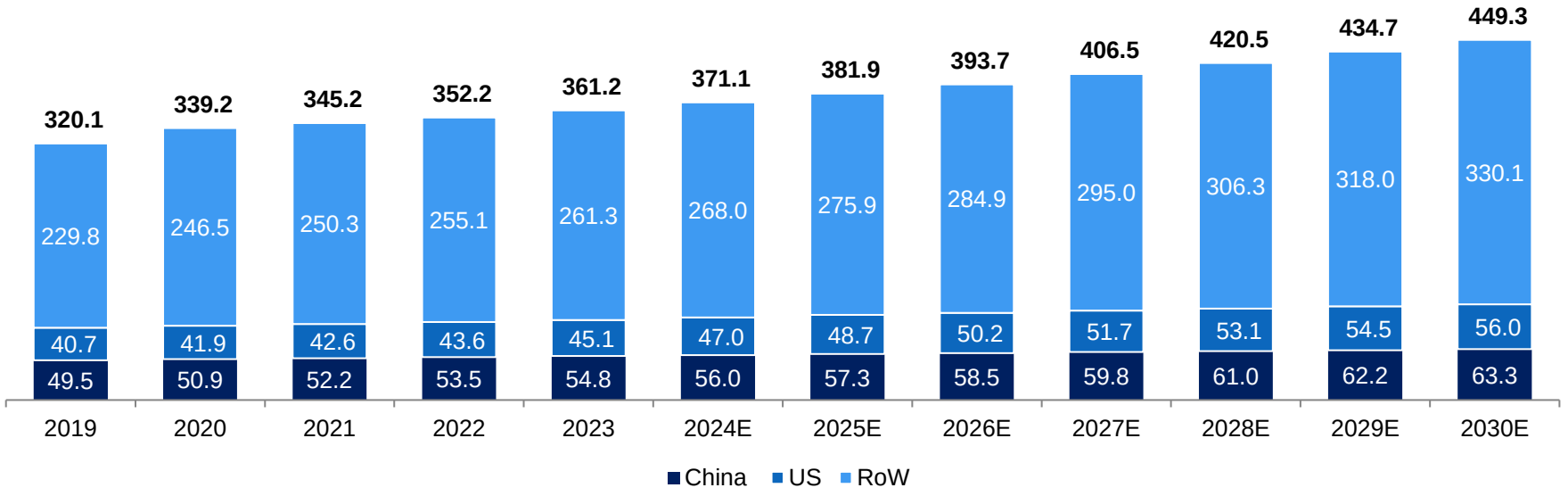
- It is not clear if one test is more accurate than the other, but FISH is more expensive and takes longer to get the results. Often the IHC test is done first.
- If the IHC result is 0, the cancer is considered HER2-negative. These cancers do not respond to treatment with drugs that target HER2.
- If the IHC result is 1+, the cancer is considered HER2-negative. If the IHC result is 2+, the HER2 status of the tumor is not clear and is called "equivocal." This means that the HER2 status needs to be tested with FISH to clarify the result. Some breast cancers that have an IHC result of 1+ or an IHC result of 2+ along with a negative FISH test might be called HER2-low cancers.
- If the IHC result is 3+, the cancer is HER2-positive. These cancers are usually treated with drugs that target HER2.

Source: Literature Review, Frost & Sullivan analysis

Global Incidence of TNBC by Region, 2019-2030E

Global Incidence of TNBC by Region, 2019-2030E

Period	CAGR			
	China	US	RoW	Total
2019-2023	2.5%	2.6%	3.3%	3.1%
2023-2026E	2.2%	3.7%	2.9%	2.9%
2026E-2030E	2.0%	2.7%	3.7%	3.4%



Source: IARC, Frost & Sullivan Analysis

Treatment Paradigm of Advanced TNBC in China

Classification	Recommendation Class I	Recommendation Class II	Recommendation Class III

Paclitaxel treatment sensitive	• 1. Single-agent Taxanes
	  • Albumin-bound Paclitaxel
	  • Docetaxel
	  • Paclitaxel
	• 2. Combined Treatment
	  • TX regimen
	  • GT regimen
	  • TP regimen
		• 1. Single-agent Treatment
		  • Capecitabine
		  • Vinorelbine
		  • Gemcitabine
		  • Etoposide
		• 2. Combined Treatment
		  • Albumin-bound Paclitaxel + PD-1 inhibitor
		  • Taxane + Bevacizumab
			• Olaparib
			• Liposomal Paclitaxel
			• Liposomal Doxorubicin
			• Chemotherapy + PD-1 inhibitor

Paclitaxel treatment failure	• 1. Single-agent Treatment
	  • Eribulin
	  • Vinorelbine
	  • Gemcitabine
	  • Capecitabine
	• 2. Combined Therapy
	  • NP
	  • GP
	  • Utidelone + Capecitabine
	  • NX
		• 1.Single-agent Treatment
		  • Albumin-bound Paclitaxel
		  • Sacituzumab Govitecan-hziy
		  • Etoposide
		• 2. Combined Treatment
		  • Capecitabine + Bevacizumab
		  • Albumin-bound Paclitaxel + other chemotherapy
			• Olaparib
			• Liposomal Doxorubicin
			• Liposomal Paclitaxel
			• Chemotherapy + PD-1 inhibitor

Note: T: Taxanes, including Albumin-bound Paclitaxel, Docetaxel, Paclitaxel; X: Capecitabine; G: Gemcitabine; N: Vinorelbine; P: Platinum agents, including Carboplatin, Cisplatin

Source: CSCO2023, Frost & Sullivan Analysis

Treatment Paradigm of Advanced TNBC in the US

	Systemic therapy options: HR- with HER2- (TNBC)
Preferred options	• Anthracyclines such as Doxorubicin or Liposomal Doxorubicin • Taxanes, such as Paclitaxel • Anti-metabolites such as Capecitabine or Gemcitabine • Microtubule inhibitors such as Vinorelbine or Eribulin • For PD-L1-positive, Pembrolizumab with chemotherapy • For germline BRVA1 or BRCA2 mutations, Olaparib, Talazoparib, Cisplatin, or Carboplatin • Sacituzumab govitecan-hziy • Fam-trastuzumab deruxtecan-nxki (T-DXd)
Other recommended	• Cyclophosphamide • Docetaxel • Albumin-bound Paclitaxel • Epirubicin • Ixabepilone
Used in some cases	• Doxorubicin and Cyclophosphamide • Epirubicin and Cyclophosphamide • Cyclophosphamide, Methotrexate, and Fluorouracil • Docetaxel and Capecitabine • Gemcitabine and Paclitaxel • Gemcitabine and Carboplatin • Carboplatin and Paclitaxel or Albumin-bound paclitaxel

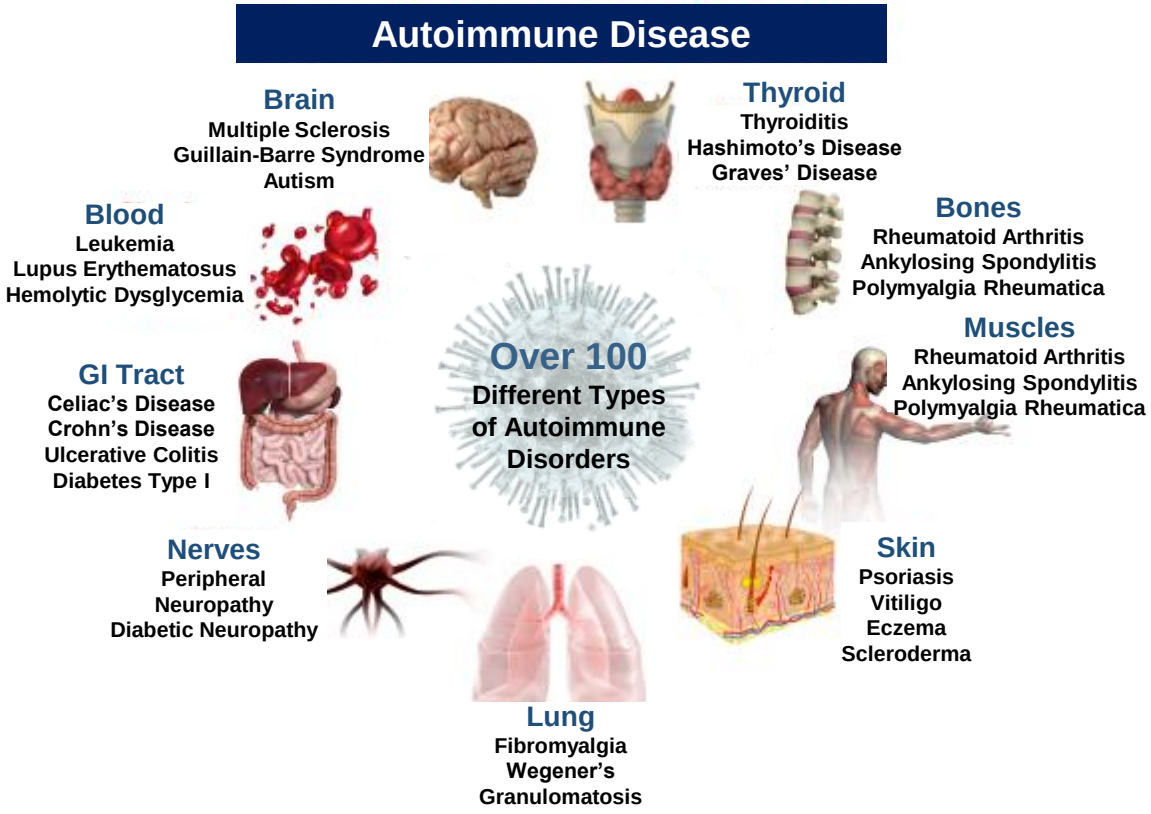
Source: NCCN2023, Frost & Sullivan Analysis

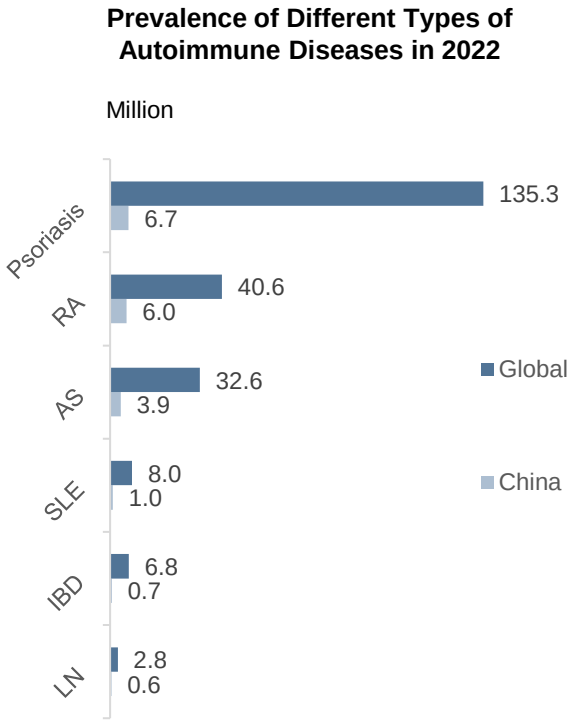
Table of Contents

Overview of Autoimmune Disease

Major Type and Prevalence Cases

- An autoimmune disease is a condition in which the body's immune system mistakenly attacks body, which can be associated with over-activity of the immune system. Autoimmune diseases are hard to diagnose, and many different types of autoimmune disease share similar symptoms.
- There are roughly 100 different types of autoimmune disorders, which can affect almost any part of the body, including the heart, brain, nerves, muscles, skin, eyes, joints, lungs, kidneys, glands, the digestive tract, and blood vessels.





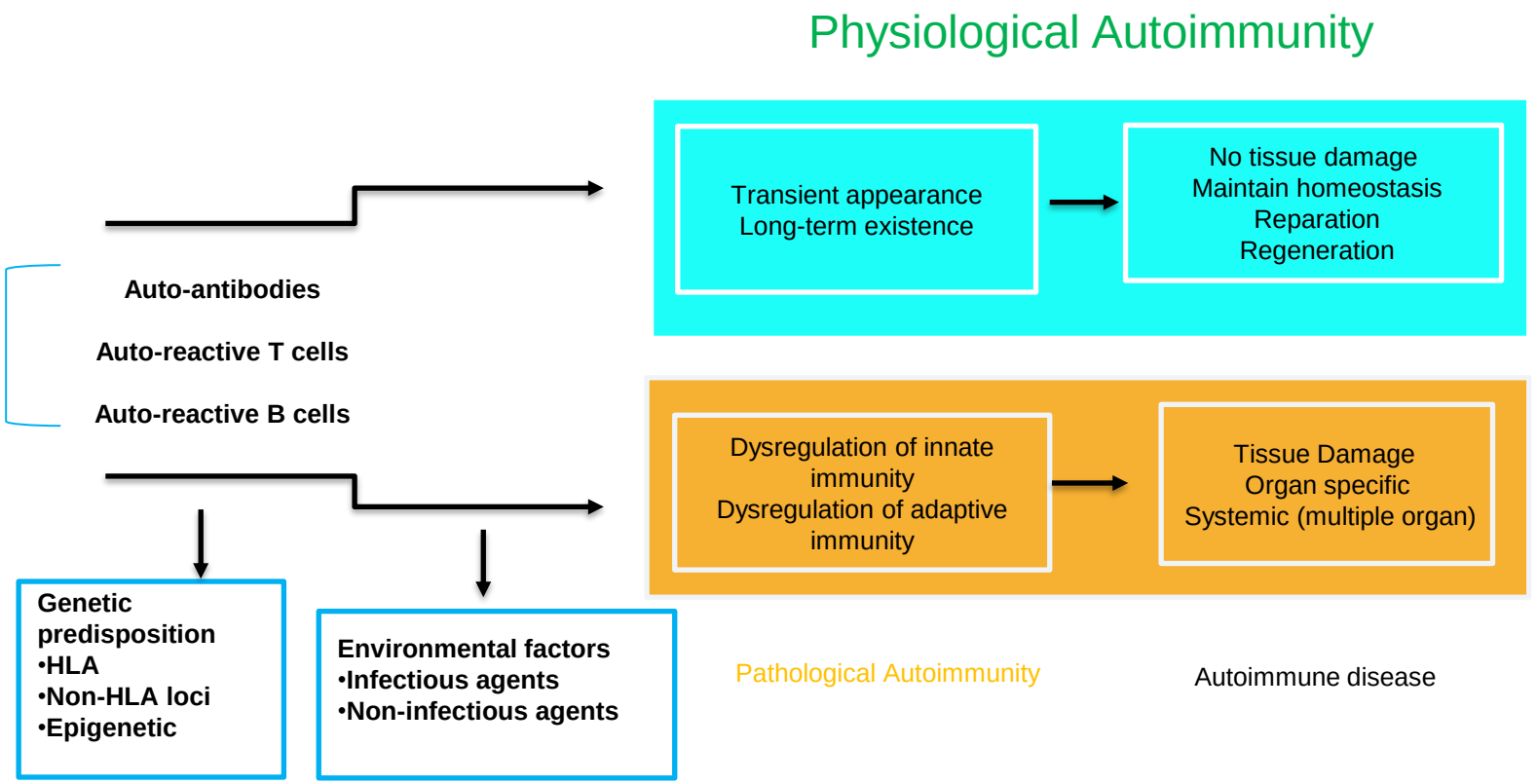
Note: RA: Rheumatoid arthritis; AS: Ankylosing spondylitis; SLE: Systemic lupus erythematosus; IBD: Inflammatory bowel diseases; LN: Lupus nephritis

Source: Literature Review, Frost & Sullivan Analysis

Overview of Autoimmune Disease

MOA and Risk Factors

- The diagram illustrates that physiological autoimmunity maintains homeostasis and repair without damage via auto-antibodies, T cells, and B cells. Pathological autoimmunity, caused by immune dysregulation, leads to tissue damage and autoimmune diseases, influenced by genetic and environmental factors.



Source: Literature Review, Frost & Sullivan Analysis

Treatment Revolution for Auto-immune Disease

Anti-inflammatory Agents

- Treatments were generally effective for alleviating of pain, fever, and inflammatory responses, but were limited to treating the symptoms of the disease.

Salicylates → **NSAIDs**, **Glucocorticoids**, **DMARDs**

- Active components of Willow spp.
- Identified in the mid-19th century

- Due to the chemical advances in the 19th–20th centuries.

Targeted Biologics

- Targeted Biologics target the underlying sources of autoimmune disease, which improves physical functioning and prevents irreversible damage, making disease remission possible.

Anti-TNF Antibodies

- Total five innovative TNF-targeting drugs have been approved.

Interleukin Related Drugs

- Include marketed drugs targeting at IL-1, IL-6,IL-17, IL-23, etc.

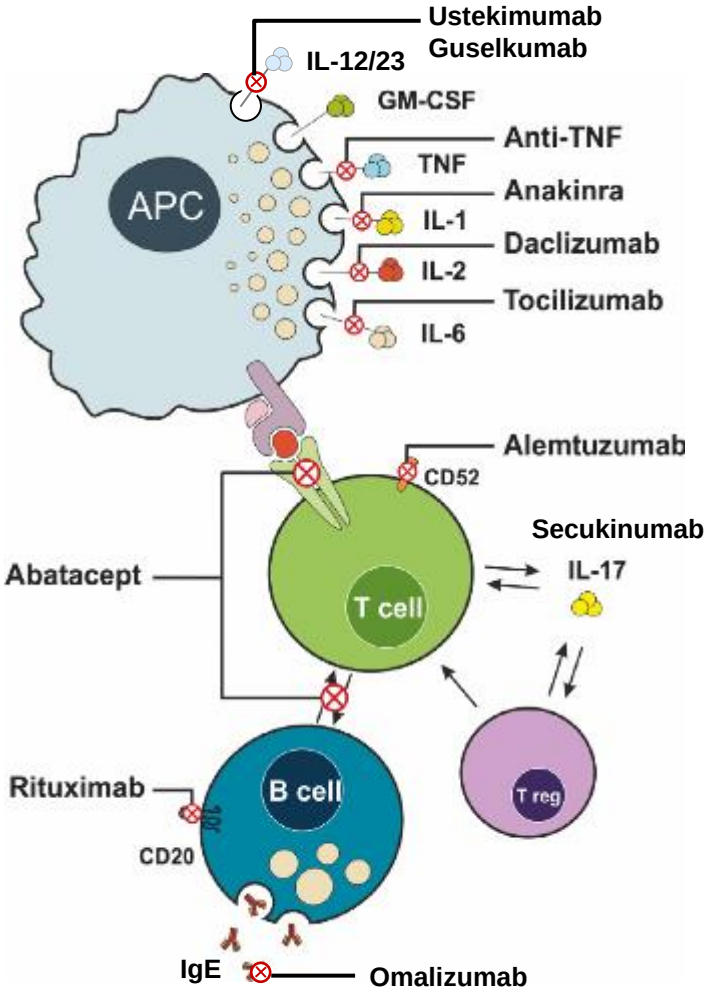
JAK Inhibitors

- Include JAK1, JAK2, TYK2 and JAK3.

Others

- Include other monoclonal antibodies targeting at CD20, CD22, CD28, BLyS, BTK inhibitors etc.

Future: More effective therapies being developed



Note:
NSAIDs: Non-steroidal anti-inflammatory drugs
DMARDs: Disease-modifying anti-rheumatic drugs

Source: Literature Review, Frost & Sullivan analysis

Comparison of Autoimmune Disease Treatment

Treatment Category	Common Types	Common Drugs	Mechanism	Advantages
Biologics	Biologics	• Adalimumab • Etanercept • Golimumab • Infliximab	Target at molecules involved in the activation of the immune system, such as tumor necrosis factor (TNF), interleukin (IL), B-cells and T-cells.	Newly emerging effective biologic drugs are available for patients with severe or resistant diseases.
Small Molecular	Nonsteroid anti-inflammatory drugs (NSAIDs)	• Aspirin • Ibuprofen • Naproxen	Block prostaglandins, which can sensitize the nerves and magnify pain feelings during inflammation.	Work quickly and generally have fewer side effects than corticosteroids.
	Conventional DMARDs	• Methotrexate • Leflunomide	Inhibit the enzymes that affects DNA-synthesis for the proliferation of white blood cells, thus causing immunosuppression.	Long-term medication can effectively control symptoms and achieve stable efficacy.
	Corticosteroids	• Methylprednisolone • Dexamethasone • Prednisone	Stop the release of molecules that cause inflammation and also stop body from having an immune response.	Fast and strong anti-inflammatory effect that can be applied in many situations.
	JAK inhibitors	• Tofacitinib • Baricitinib	Inhibit immune cell function by inhibiting signal transduction of cytokines and growth factors.	Have shown satisfactory efficacy in patients resistant to other medications.
	Other Immuno-suppressants	• Such as mTOR inhibitors (Sirolimus, Everolimus)	Block the mammalian target of rapamycin (mTOR) which regulates cellular metabolism, growth, and proliferation.	Have shown tumor responses in clinical trials against both autoimmune diseases and various tumor types.

Source: Literature Review, Frost & Sullivan analysis

Autoimmune Disease Treatment Diagram

Traditional Anti-inflammatory Agents

Traditional anti-inflammatory agents could alleviate pain, fever and inflammatory responses. However, studies have found that non-steroidal anti-inflammatory drugs (NSAIDs) and disease-modifying antirheumatic drugs (DMARDs) showed limited efficacy as compared to biologic drugs, especially in patients with more advanced autoimmune diseases, and there remain concerns over the potential side effects from long-term use of corticosteroids.
Mainly include:
– NSAIDs
– DMARDs
– Corticosteroids

Biologic Drugs TNF-targeting Antibodies

Antibodies targeting TNF, a type of pro-inflammatory cytokine, are the most widely used biologic drugs for the treatment of various autoimmune diseases, such as ankylosing spondylitis and rheumatoid arthritis.
Mainly include:
– Adalimumab
– Infliximab
– Golimumab
– Certolizumab
– Etanercept

Biologic Drugs Interleukin-targeting Antibodies

IL-targeting antibodies have the potential to be the next-generation biologics for the treatment of autoimmune diseases.
Mainly include:
– IL-17 antibodies
– IL-12 antibodies
– IL-23 antibodies
– IL-4 antibodies

Small-molecule Targeted Drugs

A limited number of small-molecule targeted drugs, such as janus kinase (JAK) inhibitors and PDE-4 inhibitors, have also been explored as potential treatment for various autoimmune diseases such as RA, AS and Ps. However, their potential to become recommended treatment options for autoimmune diseases is still under evaluation due to concerns over their safety profile.

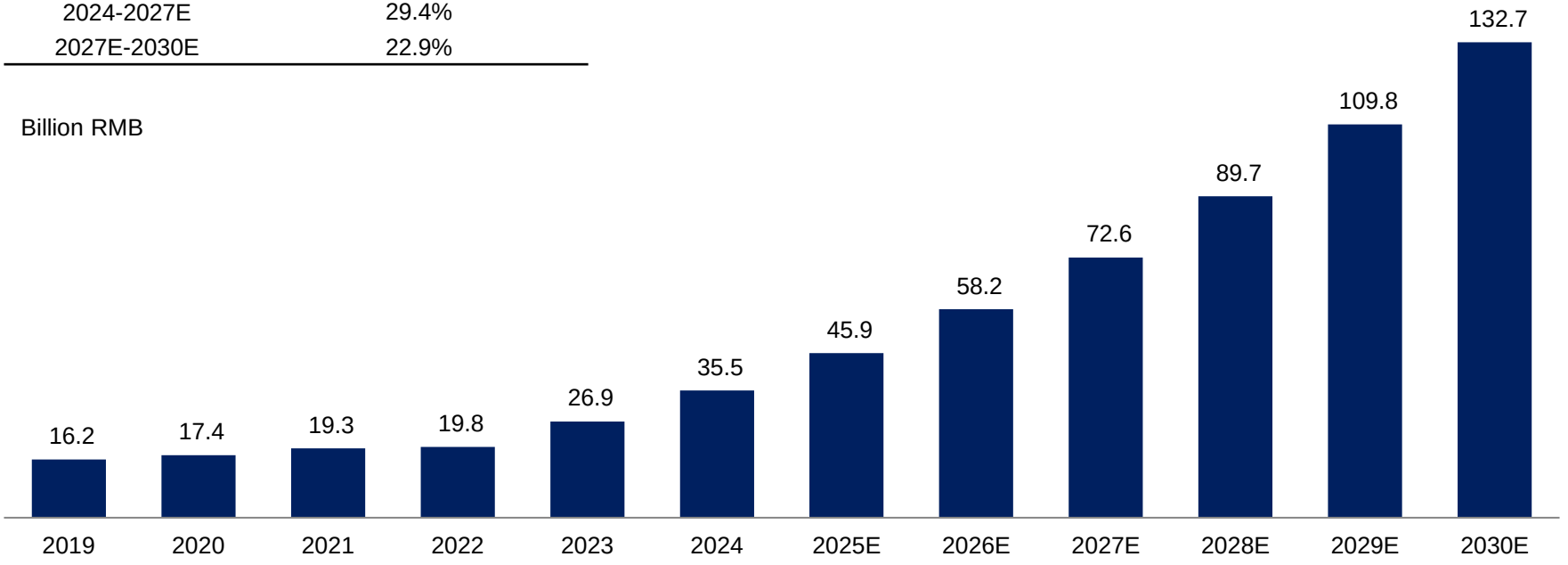
Source: Literature Review, Frost & Sullivan analysis

Historical and Forecasted of China Autoimmune Disease Drug Market Size, 2019-2030E

- China's autoimmune disease drug market size reached RMB35.5 billion in 2024, with a CAGR of 13.4% from 2019 to 2024. The market size will climb to RMB72.6 billion and RMB132.7 billion in 2027 and 2030 respectively.

Historical and Forecasted of China Autoimmune Disease Drug Market Size, 2019-2030E

Period	CAGR
2019-2024	13.4%
2024-2027E	29.4%
2027E-2030E	22.9%



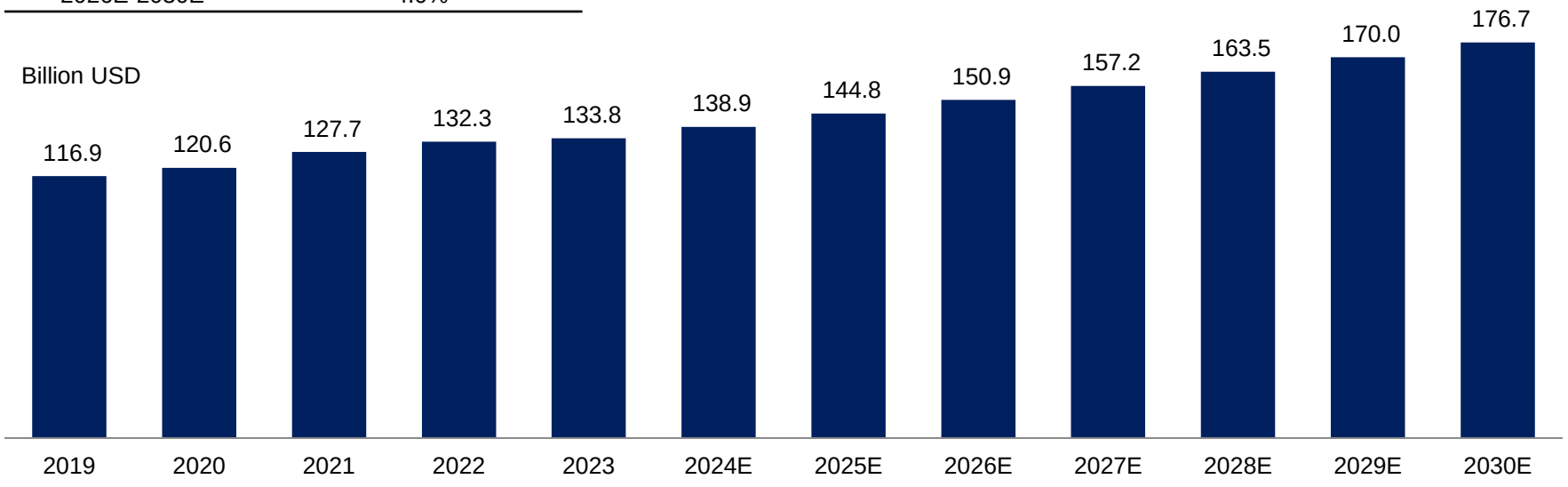
Source: Frost & Sullivan Analysis

Historical and Forecasted of Global Autoimmune Disease Drug Market Size, 2019-2030E

- The global autoimmune disease drug market size reached USD133.8 billion in 2023, with a CAGR of 3.4% from 2019 to 2023. The market size is expected to reach USD150.9 billion in 2026, with a CAGR of 4.1% from 2023 to 2026. The market will further grow to USD176.7 billion in 2030, with a CAGR of 4.0% from 2026 to 2030.

Historical and Forecasted of Global Autoimmune Disease Drug Market Size, 2019-2030E

Period	CAGR
2019-2023	3.4%
2023-2026E	4.1%
2026E-2030E	4.0%



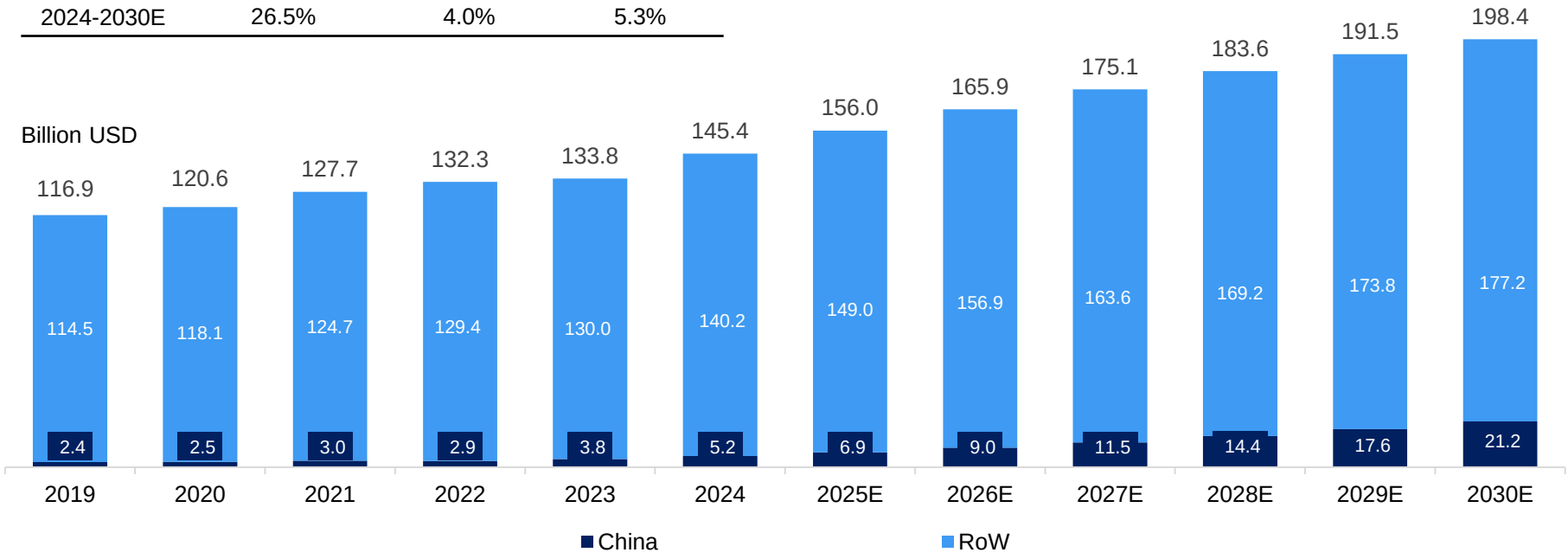
Source: Frost & Sullivan Analysis

Historical and Forecasted of Global Autoimmune Disease Drug Market Size, 2019-2030E

- The global autoimmune disease drug market size reached USD145.4 billion in 2024, with a CAGR of 4.5% from 2019 to 2024. The market size is expected to reach USD198.4 billion in 2030, with a CAGR of 5.3% from 2024 to 2030. China's autoimmune disease drug market size reached USD5.2 billion in 2024, with a CAGR of 17.1% from 2019 to 2024. The market size will climb to USD9 billion and USD21.2 billion in 2026 and 2030 respectively.

Historical and Forecasted of Global Autoimmune Disease Drug Market Size, 2019-2030E

CAGR	China	RoW	Total
2019-2024	17.1%	4.1%	4.5%
2024-2030E	26.5%	4.0%	5.3%



Source: Frost & Sullivan Analysis

Growth Drivers of Autoimmune Diseases Market

Need for personalized treatment	• For decades, numerous autoimmune disease patients have suffered from drug-related toxicity and lack of personalized treatments which are responsive to their specific diseases. Such need for personalized treatment, as well as advances in genetics and medicine, provides impetus for driving the discovery and development of effective personalized medicines for autoimmune diseases.
Lifelong treatment for autoimmune disease	• Autoimmune diseases are hard to cure. Once they become ill, most patients require long-term or even lifelong medication, and some patients are severely ill, seriously affecting their quality of life life. Autoimmune diseases have become the third most common chronic disease after cardiovascular disease and cancer.
Growing public awareness of autoimmune diseases	• There are over 100 types of autoimmune diseases, many of which are under research, including its mechanism of action as well as suitable treatment options. As the public awareness regarding disease diagnosis and management gradually increase, the diagnosis and treatment rate of autoimmune diseases tend to improve, thus, increasing number of patients will get cared and treated at the early stage. The early intervention of medication probably serve as an important driver for the whole market.
Population aging and environmental factors	• With the aging of the global population and changes in environmental factors, the incidence of autoimmune diseases is increasing year by year. Due to the long-term treatment of autoimmune diseases, the market demand for therapeutic drugs is also gradually increasing.

Source: Frost & Sullivan Analysis

Future Trends of Autoimmune Diseases Market

More indications to be covered with innovative biologics	• Currently, there is no cure for autoimmune diseases. With increased understanding of the pathophysiology of autoimmune diseases and associated biologic pathways, more innovative biologics such as anti-IL-6 antibodies, anti-IL-17 antibodies and anti-IL-23 antibodies are expected to be developed. These newly developed biologics not only provide more available drugs for patients with autoimmune diseases such as RA and systemic lupus erythematosus, but also help address more therapeutic areas.
Broad use as first-line medications	• The treatment goals for autoimmune diseases are alleviation of symptoms and maintenance of function as well as delaying the process of tissue damage. In the past few decades, drugs for the treatment of autoimmune diseases were mainly divided into three categories: nonsteroidal anti-inflammatory drugs (NSAIDs), steroidal anti-inflammatory drugs (SAIDs), and disease-modifying antirheumatic drugs (DMARDs). Nowadays, biologics are becoming available and recommended treatment options due to its better efficacy compared to previous therapy, which will greatly drive the whole market in the future since its improved affordability and accessibility.
Increasing Penetration of Biologics	• Many biologics are still under development and are expected to launch more in the near future. With more available drugs for patients with autoimmune diseases, as well as expected price reductions, biologics will have a higher penetration among patients with autoimmune diseases. • Besides, in the top-10 best selling drugs in the year of 2023, three are indicated for autoimmune diseases, and all of them those three drugs are biologics, indicating a great market potential of biologics.
Limitation of existing drug options	• NSAIDs can effectively reduce the clinical symptoms of patients, eliminate local inflammation, but unable to control the activity and progression of the disease. Steroidal anti-inflammatory drugs (SAIDs) have a rapid onset of action, but they may have many side effects and lead to disease relapse after drug withdrawal. Disease-modifying antirheumatic drugs (DMARDs) take effect quite slowly and require long-term use. Hence, there is great unmet clinical needs for innovative therapies. The market will continue to expand as more innovative therapy step into clinical use. Patients dissatisfied with the efficacy of existing treatments would benefit from it.

Source: Frost & Sullivan Analysis

Overview of Systemic Lupus Erythematosus (SLE) Symptoms

- Systemic Lupus Erythematosus (SLE) is an autoimmune disease.
- Common symptoms of SLE include rash, painful & swollen joints, fever, chest pain, hair loss, mouth ulcers, swollen lymph nodes, debilitation. With disease progression, symptoms would upgrade to organ and nerve system damages.

Progression of SLE

Common initial and chronic complaints include fever, malaise, joint pains, muscle pains, and fatigue.

Mild Symptoms

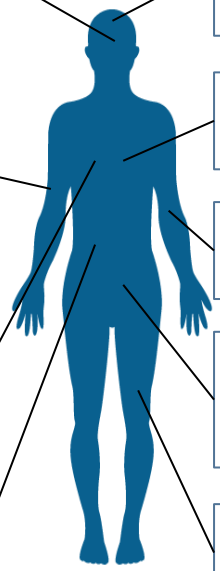
Details of organ damages are shown on the right.

Organ Damages

Mainly including severe damages to epithelial cells of the blood–brain barrier, neurological disorders, significant cognitive impairment, end-stage renal disease and catastrophic thrombosis.

Severe Outcomes

Some of the Most Common Organ Damage Symptoms



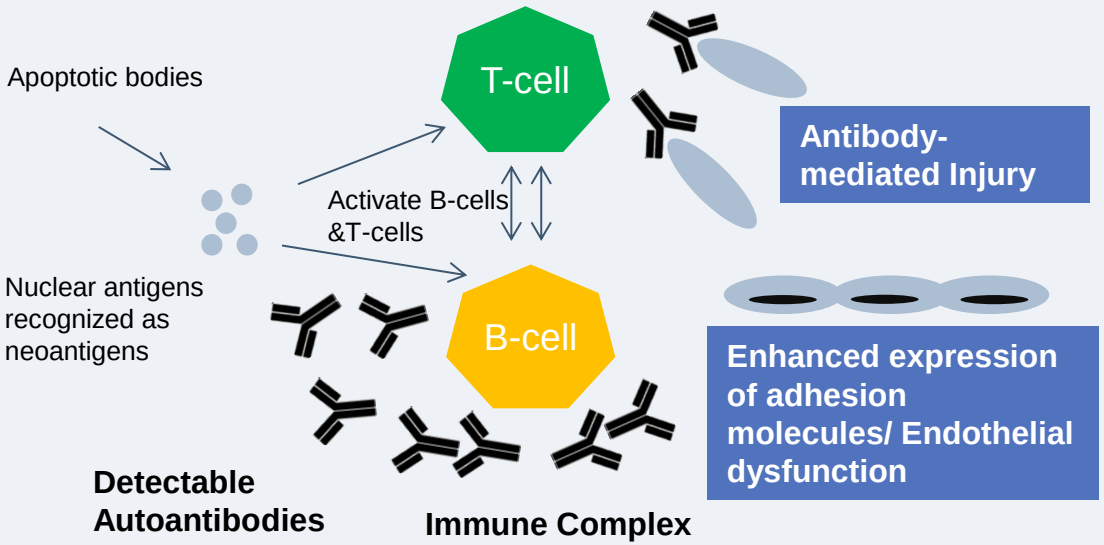
- Eyes: dry eye syndrome and secondary Sjögren's syndrome
- Skin: chronic cutaneous (discoid) lupus, subacute cutaneous lupus, and acute cutaneous lupus.
- Lung: pleuritic pain, pleurisy
- Kidney: painless passage of blood or protein in the urine
- Neuropsychiatric: headache, or other neuropsychiatric syndromes
- Heart: pericarditis, myocarditis or endocarditis
- Muscles and bones: joint pain
- Reproductive: increased rate of fetal death in utero and spontaneous abortion
- Blood: anemia is common in children with SLE

Source: Literature Review, Frost & Sullivan Analysis

Pathogenesis and Risk Factors for SLE

- In SLE, immune system is attacking its own body. This is a disease with multiple systems involved that can potentially lead to serious organ, nerve system complications, and even death.
- The cause of SLE remains unclear. Genetics and environment are considered to be possible pathogenic factors.

Pathogenesis of SLE



Failure to clear autoantibodies or immune complexes lead to tissue injury.

Risk Factors

Environment

- Infection
- Ultraviolet light
- Smoking
- Hormone
- Drug

Gene Susceptibility

- *ATG5*
- *DRAM1*
- *CDKN1B*
- *ATG7*
- *IRGM*

Source: Frost & Sullivan Analysis

SLE Stratification

- Systemic Lupus Erythematosus Disease Activity Index-2000 (SLEDAI-2000) is a global index that was developed as a clinical index for the lupus disease assessment in 2002, which is a modified version of the original SLEDAI and has been validated to be a better tool to assess SLE activities.
- Based on SLEDAI-2000, manifestations are scored only when they are new, which allows the stratification reflect the real ongoing SLE activities. SLE patients can be stratified into different stages in clinical practice: inactive, mild, moderate, and severe. Among severe SLE patients, those with acute life threatening manifestations can be called lupus crisis.

Evaluation

- Clinician evaluates manifestations which are only caused by the **SLE activities**.

Scoring

- If present, score with weight.
- Weight ranging from **1-8** of different manifestations.

Calculation

- Adding up the total score

If total score	Stratify patients to:
0	Inactive
1 - 6	Mild
7 - 12	Moderate
> 12	Severe
Crisis: Life threatening manifestations	

Stratification

- For mild and moderate SLE, the ultimate objective of the treatments is to suppress the symptoms and prevent the recurrence.
- For SLE in severe or crisis stage, treatments objective is to reduce the organs/nerves damage and prevent death.

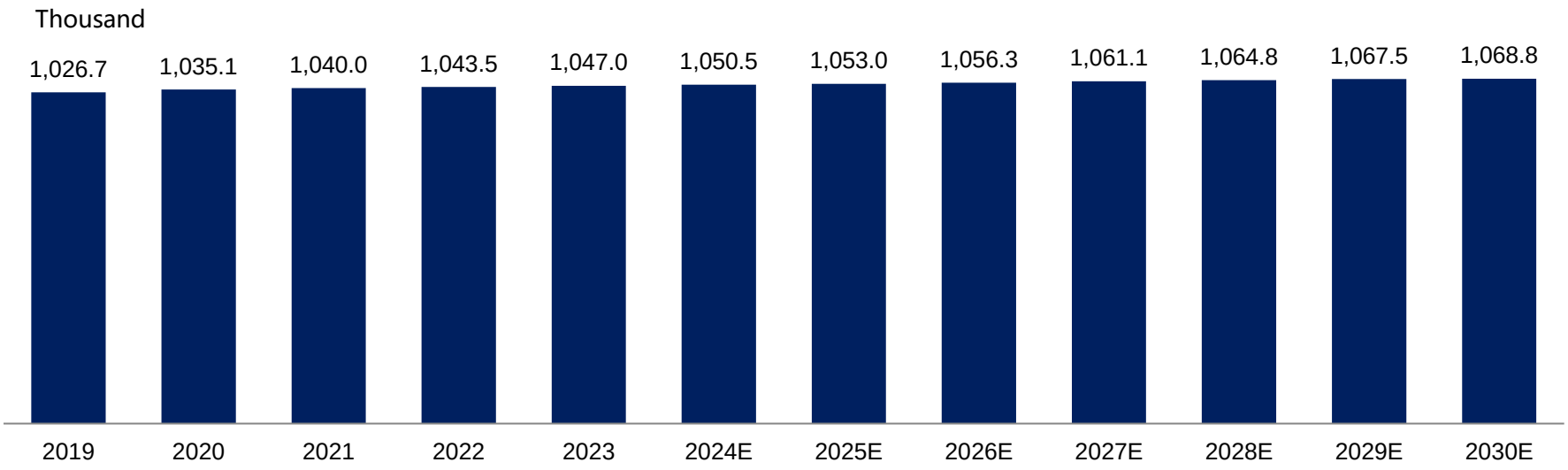
Source: Literature review, Frost & Sullivan Analysis

Prevalence of SLE in China，2018-2030E

- According to epidemiology studies, the prevalence of SLE in China had reached 1,047.0 thousand in 2023, with a CAGR of 0.5% from 2019 to 2023. The number of patients is expected to reach 1,068.8 thousand in 2030, with a CAGR of 0.3% from 2026 to 2030.

Prevalence of SLE in China，2018-2030E

Period	CAGR
2019-2023	0.5%
2023-2026E	0.3%
2026E-2030E	0.3%



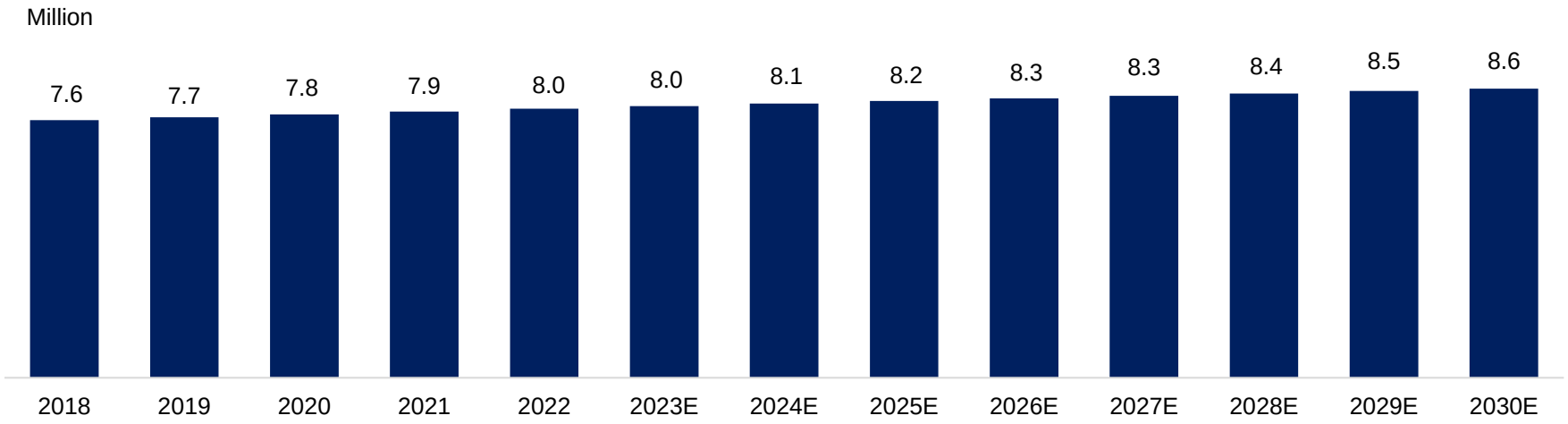
Source: Frost & Sullivan analysis

Global Prevalence of SLE, 2018-2030E

- The number of patients with SLE was 8.0 million in 2022, with a CAGR of 1.1% during 2018 and 2022. This number is expected to rise and approach 8.3 million in 2026 and 8.6 million in 2030, respectively.

Global Prevalence of SLE, 2018-2030E

Period	CAGR
2018-2022	1.1%
2022-2026E	0.9%
2026E-2030E	0.9%



Source: Literature review, Frost & Sullivan analysis

Treatment Diagram of SLE in China and U.S.

- Treating SLE often requires a team approach because of the number of organs that can be affected.

Disease Stage	Therapy Categories	Common Drugs in China an U.S.	Features
Traditional Therapy			
Mild Stage	NSAIDS	• Ibuprofen, Naproxen	The drugs are used to suppress the symptoms of SLE and prevent the recurrence.
	Antimalarial drugs	• Hydroxychloroquine	
	Immunomodulatory drugs	• Thalidomide	
	Corticosteroids	• Prednisone	
Moderate Stage	Immunomodulatory drugs (Combined with Glucocorticoid)	• Methotrexate • Azathioprine	The drugs are used for remission induction and consolidation therapy. The condition can be controlled rapidly, in addition with visceral injury reduction.
Severe Stage	Immunomodulatory drugs Corticosteroids pulse therapy Plasmapheresis	• Cyclophosphamide • Ciclosporin • Mycophenolate mofetil	Corticosteroids pulse therapy and plasmapheresis are the most common methods used to treat severe and acute SLE.
Emerging Therapy			
	Biologics	• U.S.:EULAR is viewed as the standard SLE treatment instruction worldwide. In the version of *2019 update of the EULAR recommendations for the management of SLE* listed belimumab as an effective approach to treat SLE. • China: The latest *2020 Chinese Guidelines for the Diagnosis and Treatment of Systemic Lupus Erythematosus* published by Chinese Rheumatology Association in 2020 mentioned belimumab as an innovative approach for patients who didn't benefit from traditional treatments, and the efficacy and safety for belimumab in Chinese cohorts remain further validation. Influenced by the late approval of belimumab in China, low affordability of Chinese patients, and current inadequate market education, the penetration of biologics in China is still low.	Belimumab blocks the stimulation of the B cells (a B-lymphocyte stimulator or BLyS-specific inhibitor) and is approved for the treatment of adults with active autoantibody-positive systemic lupus erythematosus who are receiving standard therapy. It is approved in U.S. in 2011, however, in 2019 in China.

Source:《2020中国系统性红斑狼疮诊疗指南》, 2019 update of the EULAR (European League Against Rheumatism) recommendations for the management of systemic lupus erythematosus, Frost & Sullivan analysis

Overview of Systemic Lupus Erythematosus Therapies

- Systemic lupus erythematosus (SLE) is a chronic disease. Currently, the treatment objective is to induce remission. Practical treatment depends on the type of symptoms you have and how serious they are. A few combination medications can also be used to control SLE and prevent tissue damage.

Therapy Categories	Common Drugs	MOA
NSAIDS	• Ibuprofen • Naproxen	• Help to decrease joint swelling, joint pain, fever, and inflammation of the heart and lung linings.
Corticosteroids	• Prednisone • Cyclophosphamide • Cyclosporine	• Regulate the immune system to control inflammation in the body
Antimalarial drugs	• Hydroxychloroquine	• Effective for SLE related arthritis, fatigue, rashes, and mouth sores.
Biological therapy	• Belimumab	• Belimumab is a BAFF inhibitor, which showed statistically significant, albeit modest, efficacy for the treatment of SLE. It represents a step forward in advance against SLE.

Source: Frost & Sullivan analysis

Limitations of Current Systemic Lupus Erythematosus Therapies (1/2)

- SLE is a chronic disease, with complex underlying pathogenic mechanisms and no effective cure currently.
- Current therapies aim to suppress inflammation, prevent recurrence and reduce symptoms, with the objective of preventing permanent organ and nerve system injury.
- Limited by the research of SLE, the current standard of care is not able to meet the needs in clinical practice. Lack of adherence, which could result from either adverse effects or economic reasons, may contribute to treatment failure.

Limitations of Traditional Therapies

- Traditional therapies for SLE could be categories into three types: NSAIDS, corticosteroids, and antimalarial drugs. All of which retain a role as non-specific drugs for certain SLE features.
- Current SLE treatment regimens follow an 'add-on' paradigm. Therapies are typically added with the disease progression. Most treatments, particularly corticosteroids and immunosuppressants, normally accompany with severe side effects that bring more damages to the patients.
- Patients treated by corticosteroids and other immunosuppressants, are at high risk of infections due to suppressed immune system.
- Constant corticosteroids treatment leads to obesity and disturbance of patients' mental health.
- Osteoporosis is another major comorbidity with long-term use of corticosteroids.

✓ *Few options exist for disease control for patients who fail to well respond to currently available and approved therapies or who are unable to tolerate the adverse effects related to current therapies.*

Source : Frost & Sullivan Analysis

Limitations of Current Systemic Lupus Erythematosus Therapies (2/2)

Limitations of Current Targeted Therapies

Limited Marketed Drug
- Benlysta is the only approved targeted therapy for SLE. There is no other approved therapies on market yet.

Complicated Administration
- Benlysta is normally administrated via subcutaneously or intravenous infusion: a healthcare provider can perform the injection and patients must get trained before self-operation at home.
- The infusion can take up ~1 hour to complete.
- Complicated administration may cause patients less compliable in long-term treatment.

Affordability
- Annual cost of Benlysta can reach up to $42,000 (drug only) which is much more higher than traditional drugs such as corticosteroids and immunosuppressive agents.
- The injection operation of Benlysta requires professional assistance, which brings more cost on patients' bill.
- As SLE is a chronic disease, patients need long-term treatments. The high price will lead to constant financial distress and may cause patients quit Benlysta regimen.

Adverse Effects
- The use of Benlysta may bring adverse effects: infection, hypersensitivity reaction, mental disorders, and nausea.

Limited Approved Indications
- Benlysta is only approved in treating SLE patients with no severe organ damage, lupus nephritis, CNS damage, or other severe conditions. Limited approved indication limits the penetration of Benlysta in clinical practice.

Source: Literature Review, Frost & Sullivan analysis

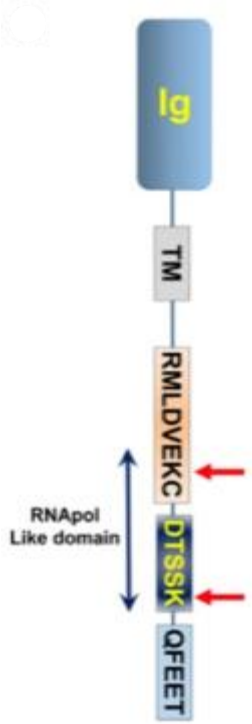
Table of Contents

Overview of PD-L1/4-1BB

PD-L1 Structure

- Programmed death-ligand 1 (PD-L1) is a 40kDa type 1 transmembrane protein that has been speculated to play a major role in suppressing the adaptive arm of immune systems.

PD-L1 Structure



PD-L1 primary structure includes:

Extracellular domain:

- PD-L1 adopts an immunoglobulin structure, consisting of an Ig variable (V) distal region and an Ig constant (C) proximal region. The V sequence forms a standard Ig-like domain with complementary determining-like regions (CDRs) that constitute the binding domain to PD-1.

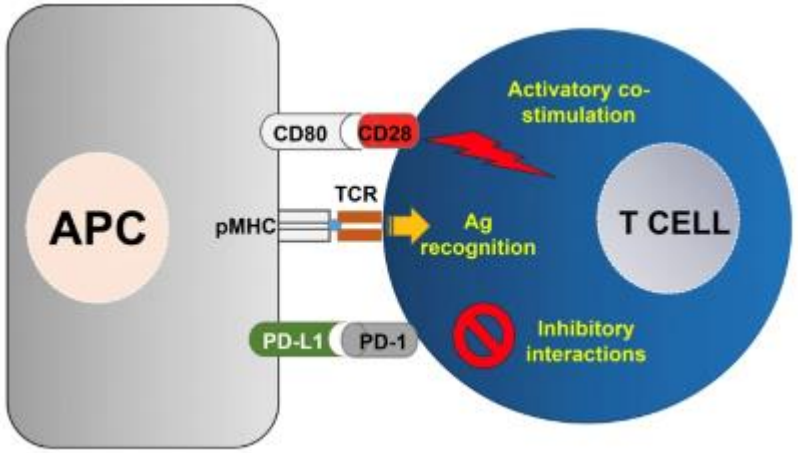
Transmembrane domain:

- PD-L1 is anchored to the cell membrane by a hydrophobic transmembrane sequence.

Intracellular domain:

- The region of PD-L1 is relatively short and has very low sequence similarity to that of other B7 molecules. However, this region contains three conserved sequences, including the RMLDVEKC, DTSSK, and QFEET motifs. These motifs may transmit survival signals through functions associated with them.

PD-L1 Inhibitor



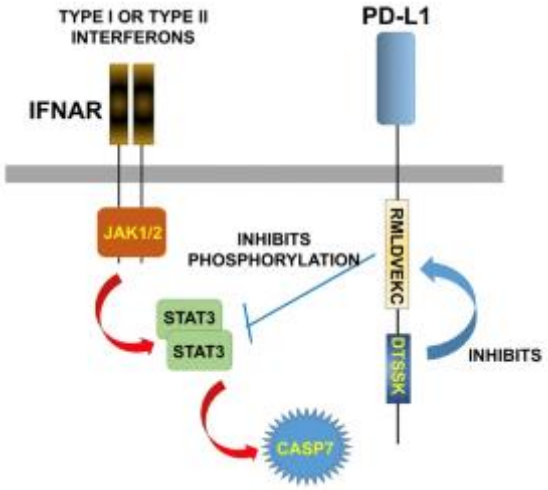
PD-1 is a checkpoint protein found on T cells, serving as an "off switch" to prevent these immune cells from attacking other cells in the body. It achieves this by binding to PD-L1, a protein present on both normal and cancer cells. When PD-1 binds to PD-L1, it signals the T cell to refrain from attacking the other cell. Cancer cells often produce high levels of PD-L1, allowing them to evade immune attacks.

Source: Literature Review, Frost & Sullivan Analysis

Overview of PD-L1/4-1BB

PD-L1 Pathway

PD-L1 Pathway



PD-L1 counteracts interferon-mediated apoptosis

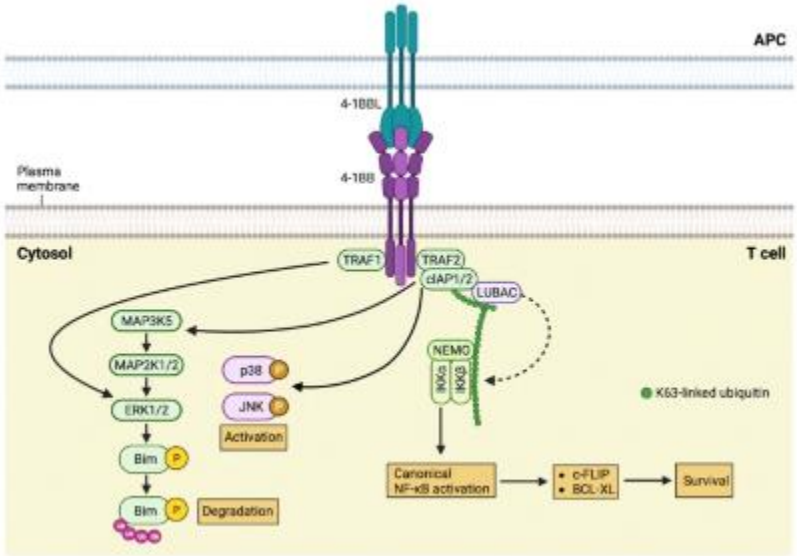
- It uses a part called the RMLDVEKC motif to stop STAT3 from working, which stops cell death caused by caspases. Another part called the DTSSK motif helps control the RMLDVEKC motif.

Tumor necrosis factor receptor superfamily (TNFR)

The TNF receptor superfamily includes membrane proteins that regulate cell death pathways, gene expression, and immune responses. They interact with TNF-related cytokines and some members of the Ig superfamily. These receptors are crucial for immune system development and host defense against pathogens. Mutations in TNF genes are linked to human diseases, and viruses target TNF family members to evade immune responses. Dysregulation of TNFRSF signaling can lead to autoimmune diseases, and TNF inhibitors are used to treat such conditions.

4-1BB mechanism

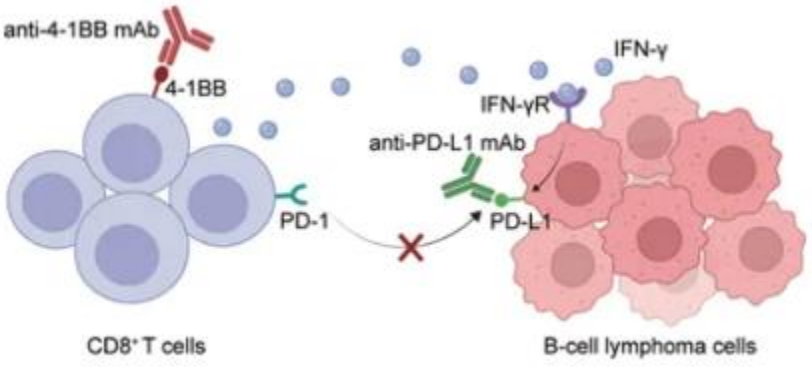
- 4-1BB is a member of the tumor-necrosis factor receptor (TNFR) superfamily.
- The mechanism involves the interaction between the 4-1BB receptor on T cells and its ligand, 4-1BBL, typically found on antigen-presenting cells (APCs). When these molecules bind, they initiate a signaling cascade that promotes T cell activation, survival, and proliferation.



Source: Literature Review, Frost & Sullivan Analysis

Overview of PD-L1/4-1BB

Mechanism of PD-L1/4-1BB dual antibodies



- The PD-L1/4-1BB dual antibody is an immunotherapy that combines two antibodies targeting PD-L1 and 4-1BB, respectively. The PD-L1 antibody blocks the interaction between PD-L1 on tumor cells and the PD-1 receptor, thereby preventing the tumor cells from suppressing T cell activity via the PD-L1/PD-1 signaling pathway. Meanwhile, the 4-1BB antibody binds to the 4-1BB receptor, activating anti-tumor immune responses in T cells. This dual action enhances T cell-mediated attack on tumor cells, promoting immune clearance of tumors.
- Main indications: non-small cell lung cancer, melanoma, head and neck squamous cell carcinoma, among others

Limitations of 4-1BB Monotherapy

- The use of 4-1BB monoclonal antibodies in cancer therapy is fraught with significant challenges, particularly safety concerns.
- One of the primary issues is the potential for immune system overstimulation, which can lead to severe inflammatory responses. Additionally, liver toxicity remains a critical concern.

Advantages of PD-L1/4-1BB Dual Antibody Compared to PD-1/PD-L1 Monotherapy

- Recognized for its wide expression and key role in eliciting T-cell responses, 4-1BB-targeted therapies show significant potential, especially in cancers where PD-1/PD-L1 inhibitors are effective.
- These therapies aim to meet unmet medical needs by fully leveraging the body's immune system to provide more effective and lasting responses against cancer while containing favorable safety profile.
- Specifically, bispecific antibodies targeting both PD-L1 and 4-1BB are highly promising due to their ability to harness complementary immunosuppressive pathways, effectively addressing the limitations of PD-1/PD-L1 monotherapy, which typically demonstrates modest response rates and can lead to resistance.
- Dual targeting of PD-L1 and 4-1BB not only permits tumor cell-mediated 4-1BB activation, thereby avoiding off-target liver toxicity, but also enables optimal engagement of antitumor immunity.

Source: Literature Review, Frost & Sullivan Analysis

Competitive Landscape of China PD-L1/4-1BB Bispecific Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	Mono or Combo Therapy in Trial Design	First Posted Date
LBL-024	PD-L1/4-1BB	Leads Biolabs CO., LTD.	Registrational trial	Advanced EP-NEC	Combo	2024-07-11
			Phase 2	Advanced Solid Tumor	Combo	2025-01-21
QLF31907	PD-L1/4-1BB	Qilu Pharmaceutical CO., LTD	Phase 2	Advanced Melanoma and UC	Mono	2023-03-21
PM1003	PD-L1/4-1BB	Biotheus Inc.	Phase 1/2	Advanced Solid Tumor	Mono	2021-09-30
ATG-101	PD-L1/4-1BB	Antengene Biologics Limited	Phase 1	Advanced Solid Tumor and B-cell Lymphoma	Mono	2022-03-29
HK010	PD-L1/4-1BB	Anke Biotechnology CO., LTD	Phase 1	Advanced Solid Tumor	Mono	2023-02-06

Note: UC: Urothelial carcinoma; NEC: Neuroendocrine carcinoma

1. Conditional approval: drugs allows earlier access to promising new treatments that address unmet medical needs with ertain post-marketing requirements must typically be met
2. Registrational trial: a Clinical Trial that is designed to obtain sufficient data and results to support the filing of an application for Regulatory Approval

As of Mya 9th 2025

Source: CDE, Frost & Sullivan Analysis

Competitive Landscape of Global PD-L1/4-1BB Bispecific Antibody

Drug Name	Target	Company	Clinical Stage	Indication	Mono or Combo Ther Trial Design
LBL-024	PD-L1/4-1BB	Leads Biolabs CO., LTD.	Pivotal stage	Advanced EP-NEC	Combo
			Phase 2	Advanced Solid Tumor	Combo
Acasunlimab	PD-L1/4-1BB	Genmab	Phase 3	NSCLC	Combo
INBRX-105	PD-L1/4-1BB	Inhibrx Biosciences, Inc	Phase 2	NSCLC, Melanoma, HNSCC, GC, RCC, Esophageal Adenocarcinoma, NPC, Oropharyngeal Cancer	Mono
QLF31907	PD-L1/4-1BB	Qilu Pharmaceutical CO., LTD.	Phase 2	Melanoma, UC	Mono
AP203	PD-L1/4-1BB	AP Biosciences Inc.	Phase 1/2	NSCLC, HNSCC, ESCC and Other Solid Tumor	Mono
PM1003	PD-L1/4-1BB	Biotheus Inc.	Phase 1/2	Advanced Solid Tumor	Mono
MCLA-145	PD-L1/4-1BB	Merus N.V. / Incyte Corporation	Phase 1	Advanced Solid Tumor, B-cell Lymphoma	Mono
FS222	PD-L1/4-1BB	invoX Pharma Limited / F-star Therapeutics Limited	Phase 1	Advanced Solid Tumor	Mono
ABL503	PD-L1/4-1BB	ABL Bio, Inc.	Phase 1	Advanced Solid Tumor	Mono
ATG-101	PD-L1/4-1BB	Antengene Biologics Limited	Phase 1	Advanced Solid Tumor, B-cell NHL	Mono
BH3120	PD-L1/4-1BB	Hanmi Pharmaceutical Company Limited	Phase 1	Advanced Solid Tumor	Mono

Note: NSCLC: Non-small cell lung cancer; HNSCC: Head and neck squamous cell carcinoma; GC: Gastric cancer; RCC: Renal cell carcinoma; NPC: Nasopharyngeal carcinoma; UC: Urothelial carcinoma; ESCC: Esophageal squamous cell carcinoma; NEC: Neuroendocrine carcinoma; NHL: Non-Hodgkin Lymphoma

As of Mya 9th 2025

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Competitive Landscape of China 4-1BB Monoclonal Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	Mono or Combo Therapy in Trial Design	First Posted Date
LVGN6051	4-1BB	Lyvgen Biopharma Holdings Limited.	Phase 2	Recurrent and Metastatic HNSCC	Combo	2024-04-02
ADG106	4-1BB	Adagene Inc.	Phase 1/2	Advanced Solid Tumor, B-cell NHL	Combo	2021-01-11
PE0116	4-1BB	HyaMab Biotech Co., Ltd.	Phase 1/2	Advanced Solid Tumor	Combo	2023-07-10
DF003	4-1BB	Dingfu BioTarget Co., Ltd	Phase 1	Advanced Solid Tumor, NHL	Mono	2021-09-30
FTL001	4-1BB	Sound Biopharmaceuticals Co., Ltd / Chime Biologics	Phase 1	Advanced Recurrent and Metastatic Solid Tumor	Mono	2022-11-02
HOT-1030	4-1BB	Huabo Biopharm Co., Ltd.	Phase 1	Advanced Solid Tumor	Mono	2020-12-17
WBP3425	4-1BB	BioCity Biopharma	Phase 1	Advanced Solid Tumor	Mono	2020-08-07
YH004	4-1BB	Eucure Biopharma Co., Ltd	Phase 1	Advanced Solid Tumor, NHL	Mono	2022-09-29
ZG033	4-1BB	HankeMab Biotechnology Co., Ltd	Phase 1	Advanced Solid Tumor	Mono	2022-04-11
TWP-101	4-1BB	TheraWisdom Biopharma Co., Ltd.	Phase 1	Advanced Melanoma, UC and Other Solid Tumor	Mono	2021-05-25

Note: HNSCC: Head and neck squamous cell carcinoma; NHL: Non-Hodgkin Lymphoma; UC: Urothelial carcinoma

As of Mya 9th 2025

Source: CDE, Frost & Sullivan Analysis

Competitive Landscape of Global 4-1BB Monoclonal Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	Mono or Combo Therapy in Trial Design	First Posted Date
LVGN6051	4-1BB	Lyvgen Biopharma Holdings Limited	Phase 2	HNSCC	Combo	2024-04-22
EU101	4-1BB	Eutilex / Huabo Biopharm Co., Ltd.	Phase 1/2	NSCLC, RCC, Prostate cancer and Other Solid Tumor	Mono	2021-05-27
ADG106	4-1BB	Adagene Inc.	Phase 1/2	NSCLC	Combo	2022-02-11
PE0116	4-1BB	HyaMab Biotech Co., Ltd.	Phase 1/2	Locally Advanced and Metastatic Solid Tumor	Mono	2023-04-06
CTX-471	4-1BB	Compass Therapeutics	Phase 1	NSCLC, SCLC, Mesothelioma, Melanoma, HNC	Mono	2019-03-19
AGEN2373	4-1BB	Agenus Inc.	Phase 1	Advanced Cancer	Mono	2019-10-10
ATOR-1017	4-1BB	Alligator Bioscience AB	Phase 1	Advanced Solid Tumor	Mono	2019-10-30
TWP-101/ Sytalizumab	4-1BB	TheraWisdom Biopharma Co., Ltd.	Phase 1	Advanced Melanoma, UC and Other Solid Tumor	Mono	2021-05-04
YH004	4-1BB	Eucure Biopharma Co., Ltd	Phase 1	Advanced Solid Tumor, NHL	Mono	2022-10-04
ADG206	4-1BB	Adagene Inc.	Phase 1	Advanced and Metastatic Solid Tumor	Mono	2022-11-14
FTL001	4-1BB	Sound Biopharmaceuticals	Phase 1	Advanced Solid Tumors	Mono	2024-05-10

Note: HNSCC: Head and neck squamous cell carcinoma; NSCLC: Non-small cell lung cancer; RCC: Renal cell carcinoma; SCLC: Small cell lung cancer; HNC: Head and neck cancer; UC: Urothelial carcinoma; NHL: Non-Hodgkin Lymphoma

As of Mya 9th 2025

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

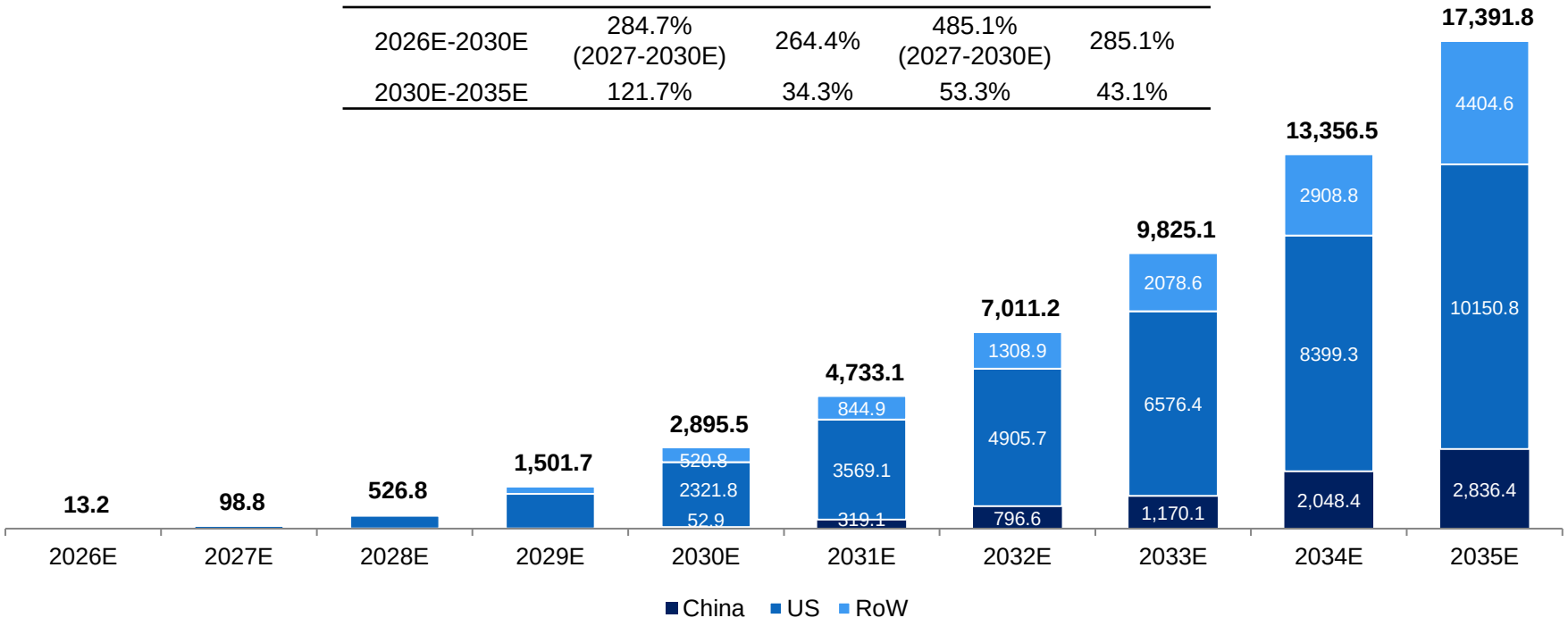
Global 4-1BB Antibody Market by Region, 2026-2035E

- The size of global 4-1BB antibody market is expected to reach USD 13.2 million, USD 2.9 billion, USD 17.4 billion in 2026, 2030 and 2035 respectively, representing a CAGR of 285.1% from 2026 to 2030, 43.1% from 2030 to 2035. The size of US 4-1BB antibody market is expected to reach USD 13.2 million, USD 2.3 billion, USD 10.2 billion in 2026, 2030, 2035 respectively, representing a CAGR of 264.4% from 2026 to 2030, 34.3% from 2030 to 2035. The size of China 4-1BB antibody market is expected to reach USD 0.9 million, USD 52.9 million, USD 2.8 billion in 2027, 2030, 2035 respectively, representing a CAGR of 284.7% from 2027 to 2030, 121.7% from 2030 to 2035.

Global 4-1BB Antibody Drug Market by Region, 2026E-2035E

Million USD

Period	CAGR			
	China	US	RoW	Total
2026E-2030E	284.7% (2027-2030E)	264.4%	485.1% (2027-2030E)	285.1%
2030E-2035E	121.7%	34.3%	53.3%	43.1%

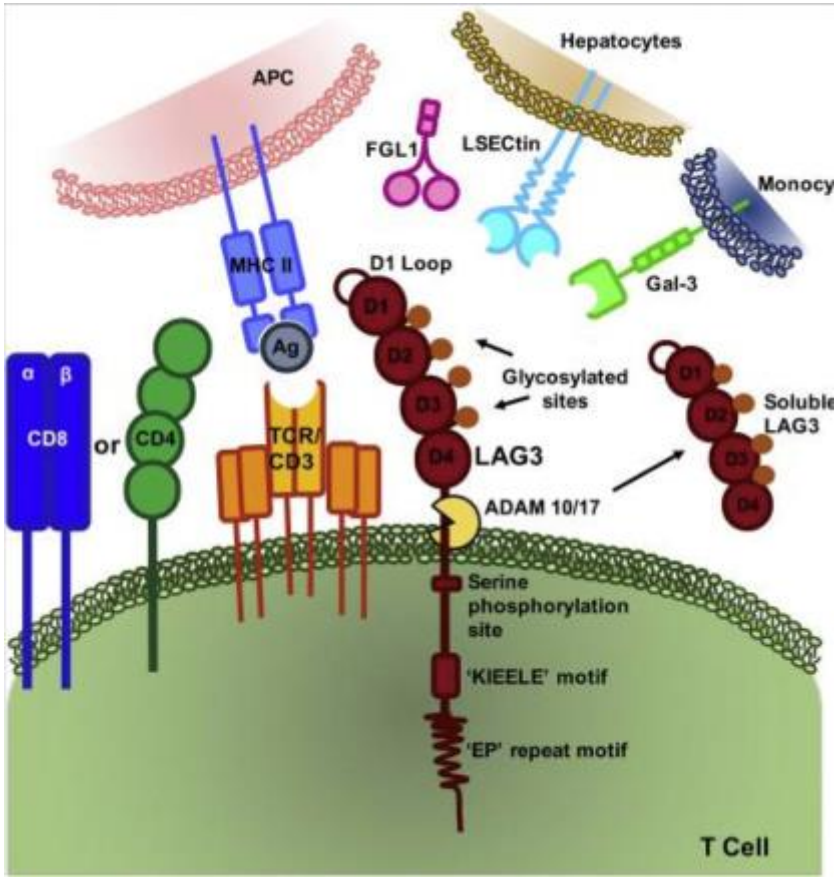


Source: IARC, Frost & Sullivan Analysis

Overview of LAG3

LAG3 Structure

- Lymphocyte Activation Gene 3 (LAG3) , an immune checkpoint receptor, functions by delivering inhibitory signals that regulate immune cell homeostasis, T cell activation, proliferation, cytokine production, cytolytic activity and other functions



LAG3 Structure

- LAG3 is composed of four Ig-like domains and contains three highly conserved regions in the cytoplasmic tail. LAG3 negatively regulates their activity through several ligands, including MHC-II, LSECtin, Gal-3, and FGL1.

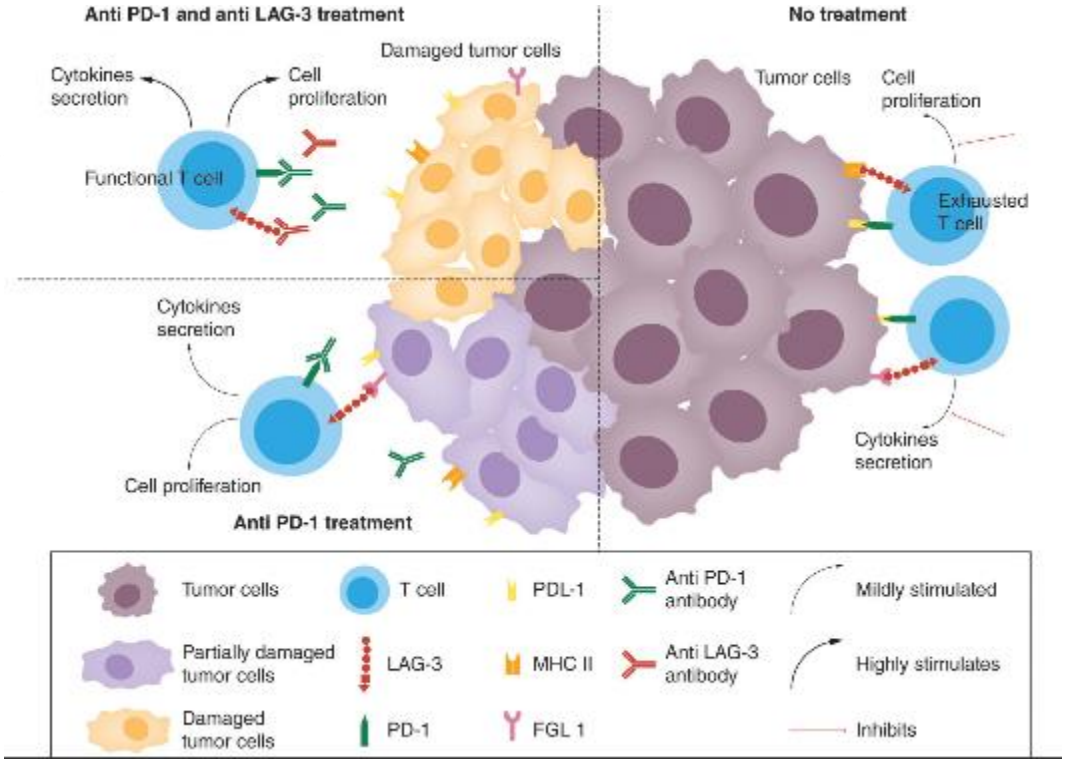
LAG3 Signaling Pathway

- The LAG-3 signaling pathway involves interactions between the LAG-3 receptor and its ligands, primarily MHC class II molecules and galectin-3. When activated, LAG-3 inhibits T cell proliferation and cytokine secretion, dampening immune responses. It also promotes regulatory T cell function and the release of immunosuppressive cytokines like IL-10 and TGF-B.
- LAG-3 acts as a negative regulator of T cell activation and contributes to immune tolerance and evasion, particularly in cancer and chronic infections.
- Due to its role in antigen presentation, chronic exposure to antigens from infections or tumors can lead to high and sustained LAG-3 expression on T-cells. This causes T-cells to become “exhausted,” losing their effector functions, which diminishes immunosurveillance and allows tumors to evade the immune system.

Source: Literature Review, Frost & Sullivan Analysis

Overview of LAG3

LAG3 and PD-L1



Potential of combining LAG3 inhibitors with PD-1

- Restoring the function of exhausted T cells: Combined LAG3 and PD-1 inhibitor therapy can restore the function of suppressed effector T cells, enabling them to effectively recognize and attack tumor cells.
- Enhancing T cell activity: The combination therapy can increase the number of activated CD8+ T cells and CD4+ T cells, enhancing their ability to attack tumor cells.
- Inhibiting resistance mechanisms: Combined LAG3 and PD-1 inhibition can prevent the development of resistance to single-antibody treatment by tumor cells, thereby enhancing treatment efficacy.
- Synergistically regulating immune function: LAG3 and PD-1 can synergistically regulate T cell function, further enhancing the immune system's ability to recognize and attack tumors.

Source: Literature Review, Frost & Sullivan Analysis

Competitive Landscape of LAG3 inhibitor Approved by FDA

Drug Name	Brand Name	Target	Company	Indications	Mono or Combo Therapy in Trial Design	Approval Date	Annual Treatment Cost in the US
Nivolumab + Relatlimab	OPDUALAG®	LAG3	BMS	Unresectable or Metastatic Melanoma	Combo	2022-03-18	Annual treatment cost is around $370 thousand

As of Oct 22nd 2024

Source: FDA, Frost Sullivan Analysis

Competitive Landscape of China LAG3 Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indications	Mono or Combo Therapy in Trial Design	First Posted Date
HLX26	LAG3	Henlius Biotech	Phase 2	NSCLC	Combo	2023-06-19
LBL-007	LAG3	Leads Biolabs Co., Ltd / BeiGene Biological Pharmaceutical Co., Ltd	Phase 2	ESCC	Combo	2023-10-13
			Phase 2	HNSCC	Combo	2023-07-12
			Phase 2	NSCLC	Combo	2023-03-29
			Phase 1/2	CRC	Combo	2022-12-29
			Phase 1/2	Advanced Solid Tumor	Combo	2021-11-15
DNV3	LAG3	CentryMed Pharmaceutical	Phase 2	Locally advanced unresectable and metastatic melanoma	Combo	2024-10-29
			Phase 1/2	Advanced Solid Tumor and Lymphoma	Mono	2020-11-25
SHR-1802	LAG3	HengRui Medicine Co., Ltd.	Phase 1/2	Advanced Solid Tumor	Combo	2023-03-23
GLS-012	LAG3	Gloria Biosciences Co., Ltd.	Phase 1/2	Advanced NSCLC	Combo	2023-08-02
KL-A289	LAG3	Kelun-Biotech Biopharmaceutical Co., Ltd	Phase 1	Advanced Solid Tumor	Combo	2021-05-07
IBI110	LAG3	Innovent Biologics, Inc.	Phase 1	r/r DLBCL	Combo	2021-09-07
			Phase 1	SCLC	Combo	2021-08-13
MIL98	LAG3	Mabworks Biotechnology Co., Ltd	Phase 1	Advanced Solid Tumor	Mono	2022-05-20
TQB2223	LAG3	Chia Tai-tianqing Pharmaceutical Co., Ltd.	Phase 1	Advanced HCC	Combo	2023-12-25
			Phase 1	Advanced Solid Tumor	Combo	2024-10-22

As of Mya 9th 2025

Source: CDE, Frost & Sullivan Analysis

Competitive Landscape of Global LAG3 Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	Mono or Combo Therapy in Trial Design	First Posted Date
Fianlimab	LAG3	Regeneron Pharmaceuticals	Phase 3	Melanoma	Combo	2024-02-07
			Phase 2/3	NSCLC	Combo	2023-03-27
			Phase 2	HCC, HNSCC	Combo	2019-04-16
LBL-007	LAG3	Leads Biolabs Co.,Ltd / BeiGene	Phase 2	NSCLC	Combo	2022-10-13
			Phase 2	HNSCC	Combo	2023-06-18
			Phase 2	Locally Advanced or Metastatic ESCC	Combo	2023-08-24
			Phase 1/2	NPC and Other Advanced Solid Tumor*	Combo	2021-11-01
			Phase 1/2	CRC	Combo	2022-11-08
BI 754111	LAG3	Boehringer Ingelheim	Phase 2	Advanced or Metastatic Solid Tumor	Combo	2018-10-05
INCAGN02385	LAG3	Incyte Corporation	Phase 2	Endometrial Cancer	Combo	2020-07-09
			Phase 2	HNC	Combo	2022-03-18
			Phase 1/2	Melanoma	Combo	2020-05-01
SHR-1802	LAG3	Hengrui Medicine Co., Ltd.	Phase 2	Advanced Solid Tumor	Combo	2022-01-26
HLX26	LAG3	Henlius Biotech	Phase 2	Advanced NSCLC	Combo	2023-03-28
IBI110	LAG3	Innovent Biologics Co. Ltd.	Phase 2	Advanced or Metastatic ESCC	Combo	2023-10-12
GLS-012	LAG3	Gloria Biosciences Co., Ltd.	Phase 1/2	Advanced NSCLC	Combo	2023-08-07

As of Mya 9th 2025

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Competitive Landscape of Global LAG3 Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	Mono or Combo Therapy in Trial Design	First Posted Date
TSR-033	LAG3	Tesaro, Inc.	Phase 1	Advanced Solid Tumor	Combo	2017-08-16
Sym022	LAG3	Symphogen A/S	Phase 1	Advanced Solid Tumor and Lymphoma	Combo	2017-10-17
TQB2223	LAG3	Chia Tai Tianqing Pharmaceutical Group Co., Ltd.	Phase 1	Advanced HCC	Combo	2024-03-20
IMP761	LAG3	Immutep S.A.S.	Phase 1	Healthy Subjects	Mono	2024-10-15

As of Mya 9th 2025

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Competitive Landscape of Respective Indications

Indication	Drug Name	Target	Company	Clinical Stage	First Posted Date
NSCLC	Fianlimab	LAG3	Regeneron Pharmaceuticals	Phase 2/3	2023/3/27
NSCLC	HLX26	LAG3	Henlius Biotech	Phase 2	2023/6/19
NSCLC	LBL-007	LAG3	Leads Biolabs Co., Ltd / BeiGene Biological Pharmaceutical Co., Ltd	Phase 2	2023/3/29
Advanced NSCLC	HLX26	LAG3	Henlius Biotech	Phase 2	2023/3/28
Advanced NSCLC	GLS-012	LAG3	Gloria Biosciences Co., Ltd.	Phase 1/2	2023/8/2
Advanced NSCLC	GLS-012	LAG3	Gloria Biosciences Co., Ltd.	Phase 1/2	2023/8/7
HNSCC	LBL-007	LAG3	Leads Biolabs Co., Ltd / BeiGene Biological Pharmaceutical Co., Ltd	Phase 2	2023/7/12
CRC	LBL-007	LAG3	Leads Biolabs Co., Ltd / BeiGene Biological Pharmaceutical Co., Ltd	Phase 1/2	2022/12/29

As of Mya 9th 2025

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Competitive Landscape of Respective Indications

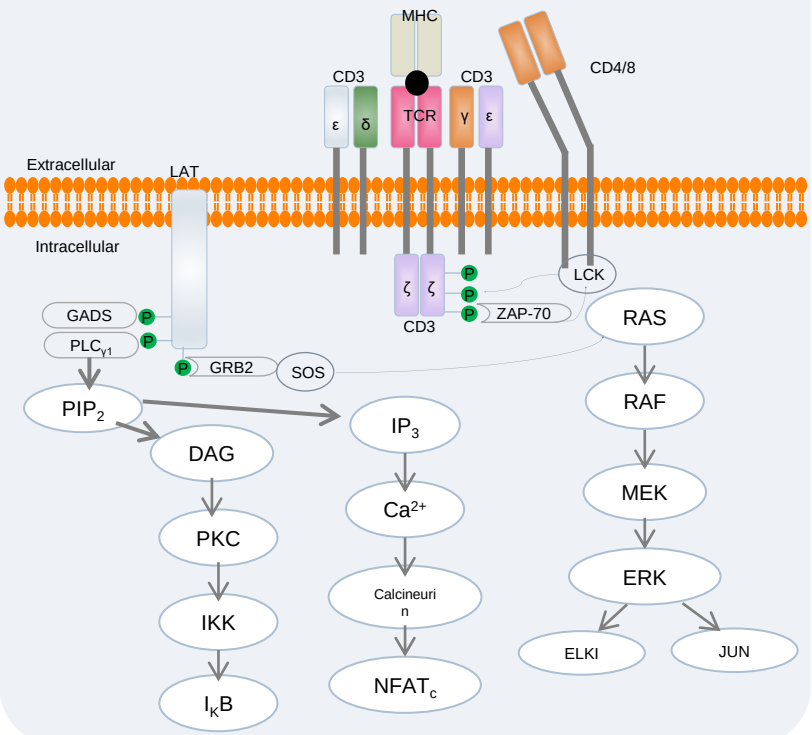
Indication	Drug Name	Target	Company	Clinical Stage	First Posted Date
ESCC	LBL-007	LAG3	Leads Biolabs Co., Ltd / BeiGene Biological Pharmaceutical Co., Ltd	Phase 2	2023/10/13
Melanoma	Fianlimab	LAG3	Regeneron Pharmaceuticals	Phase 3	2024/2/7
Locally advanced unresectable and metastatic melanoma	DNV3	LAG3	CentryMed Pharmaceutical	Phase 2	2024/10/29
Advanced or Metastatic ESCC	IBI110	LAG3	Innovent Biologics Co. Ltd.	Phase 2	2023/10/12
Advanced Solid Tumor	SHR-1802	LAG3	Hengrui Medicine Co., Ltd.	Phase 2	2022/1/26
Advanced or Metastatic Solid Tumor	BI 754111	LAG3	Boehringer Ingelheim	Phase 2	2018/10/5
Advanced Solid Tumor	SHR-1802	LAG3	HengRui Medicine Co., Ltd.	Phase 1/2	2023/3/23
Advanced Solid Tumor	LBL-007	LAG3	Leads Biolabs Co., Ltd / BeiGene Biological Pharmaceutical Co., Ltd	Phase 1/2	2021/11/15

As of Mya 9th 2025

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Overview of MUC16/CD3 Target

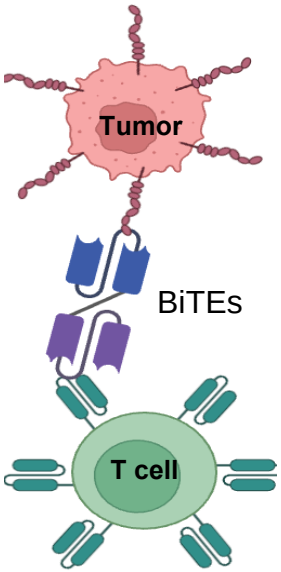
Signaling pathway of CD3



- The CD3 molecule, crucial for T cell activation and development, comprises four protein chains (CD3γ, CD3δ, CD3ε, and CD3ζ). CD3ε forms heterodimers (CD3γε and CD3δε) with CD3γ and CD3δ. T cell signaling necessitates a CD3-TCR complex due to the short intracellular domains of TCR αβ subunits.

1 *Overview of MUC16:*

- Mucin16 (MUC16), also known as carbohydrate antigen 125 (CA125), is a glycoprotein antigen that can be recognized by the monoclonal antibody OC125 detected from epithelial ovarian carcinoma antigen by Bast et al in 1981.
- CA125 is not present in normal ovarian tissue but is usually elevated in the serum of epithelial ovarian carcinoma patients. CA125 is the most commonly used serologic biomarker for the diagnosis and recurrence monitoring of epithelial ovarian carcinoma.



2 *Mechanism of MUC16/CD3:*

- BiTEs (Bispecific T-cell Engagers) are engineered proteins that connect T-cells to cancer cells, activating an immune response to specifically target and destroy the tumor cells.
- The MUC16/CD3 BiTE MUC16-positive tumor cells and CD3-expressing T-cells, enhancing immune response against cancer. By binding to MUC16 on cancer cells and CD3 on T-cells, it promotes close contact, activating T-cells to effectively attack and kill tumor cells. This dual engagement is crucial for leveraging the immune system's potential in targeting cancers like ovarian cancer and mesothelioma, where MUC16 expression is notably high.

Source: Literature Review, Frost & Sullivan Analysis

Competitive Landscape of China MUC16/CD3 Bispecific Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
LBL-033	MUC16/CD3	Leads Biolabs Co., Ltd.	Phase 1/2	Advanced Solid Tumor	2023-03-08

As of Mya 9th 2025

Source: CDE, Frost & Sullivan Analysis

Competitive Landscape of Global MUC16/CD3 Bispecific Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
REGN4018/ Ubamatamab	MUC16/CD3	Regeneron Pharmaceuticals	Phase 2	SMARCB1-Deficient Malignancies	2024-06-06
			Phase 1/2	Recurrent Ovarian Cancer, Fallopian Tube Cancer, Primary Peritoneal Cancer and Endometrial Cancer	2018-06-20
LBL-033	MUC16/CD3	Leads Biolabs Co.,Ltd	Phase 1/2	Advanced Solid Tumor	2023-03-22

As of Mya 9th 2025

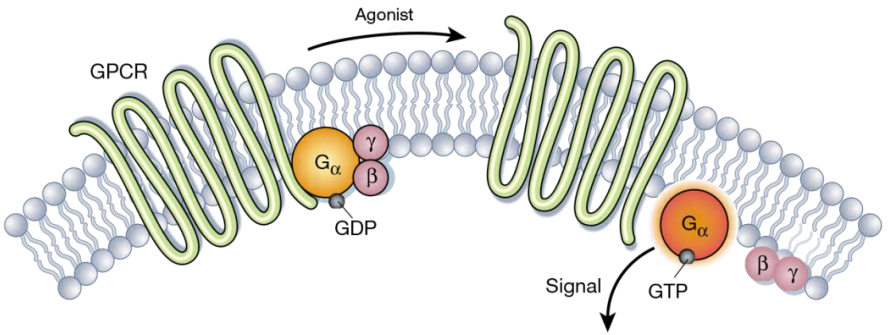
Source: ClinicalTrials.gov, Frost & Sullivan Analysis

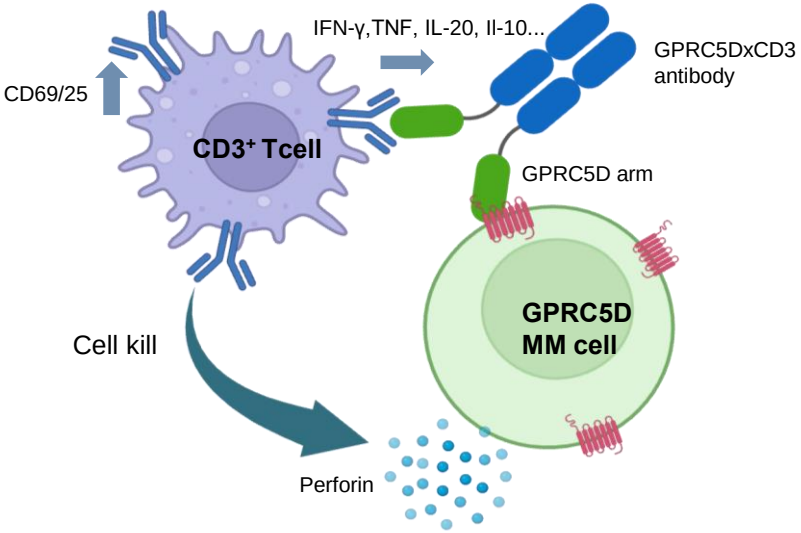
Overview of GPRC5D/CD3 Target

- The GPRC5D/CD3 target is increasingly recognized as a crucial therapeutic focus in multiple myeloma treatment, utilizing bispecific antibodies to direct and amplify the immune system's ability to identify and eliminate cancerous plasma cells.

1 *Overview of G-Protein coupled receptors Family:*

- The G-protein coupled receptors (GPCRs), one of the largest families in the mammalian genome, participate in crucial physiological functions, making them key targets for drug development. While all GPCRs have seven transmembrane domains, they vary in conserved residues within these domains.
- GPRC5D, highly expressed on multiple myeloma cells, marks it as a significant therapeutic target. This overexpression suggests a role in the cancer's growth or survival, although GPRC5D's exact function in myeloma is still under investigation.





2 *Mechanism of GPRC5D/CD3 bispecific antibody :*

- The GPRC5D/CD3 bispecific antibody represents a novel therapeutic approach, engineered to link two antigens: GPRC5D on multiple myeloma cells and CD3 on T-cells. This dual targeting facilitates the direct recruitment and activation of T-cells at the site of the tumor, leading to a potent and localized immune response against the cancer cells. The engagement of CD3 results in the activation of T-cells, which then exert cytotoxic effects specifically directed towards the myeloma cells expressing GPRC5D, thus providing a targeted strategy to combat this malignancy.

Source: Literature Review, Frost & Sullivan Analysis

Competitive Landscape of GPRC5D/CD3 Bispecific Antibody Approved by FDA

Drug Name	Brand Name	Target	Company	Indications	Approval Date	Treatment Cost
talquetamab-tgvs	TALVEY	GPRC5D/CD3	Janssen Biotech	relapsed or refractory multiple myeloma who have received at least four prior lines of therapy	2023-08-09	$270,000 to $360,000 based on the need for 6 to 8 months of treatment in the US

As of Mya 9th 2025

Source: FDA, Frost Sullivan Analysis

updated

Competitive Landscape of China GPRC5D/CD3 Bispecific Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indications	First Posted Date
Talquetamab	GPRC5D/CD3	Janssen Biotech	Phase 3	r/r MM	2022-12-29
QLS32015	GPRC5D/CD3	Qilu Pharmaceutical Co., Ltd.	Phase 2	r/r MM	2025-06-12
LBL-034	GPRC5D/CD3	Leads Biolabs Co.,Ltd	Phase 1/2	r/r MM	2023-09-19
TQB2029	GPRC5D/CD3	Chia Tai Tianqing Pharmaceutical	Phase 1	r/r MM	2024-11-04

Note: r/r MM: Relapsed or refractory multiple myeloma

As of Mya 9th 2025

Source: CDE, Frost & Sullivan Analysis

Competitive Landscape of Global GPRC5D/CD3 Bispecific Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
LBL-034	GPRC5D/CD3	Leads Biolabs Co.,Ltd	Phase 1/2	r/r MM	2023-09-22
Forimtamig*	GPRC5D/CD3	Roche	Phase 1/2	r/r MM	2023-09-26
QLS32015	GPRC5D/CD3	Qilu Pharmaceutical Co., Ltd.	Phase 1	r/r MM	2023-06-27
TQB2029	GPRC5D/CD3	Chia Tai Tianqing Pharmaceutical	Phase 1	r/r MM	2024-11-22

r/r MM: Relapsed or refractory multiple myeloma
Note: According to Roche Product Development Portfolio last updated on 23rd Octmber 2024, Forimtamig has been removed from its pipeline.

As of Mya 9th 2025

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Competitive Landscape of China GPRC5D/CD3/BCMA Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indications	First Posted Date
IBI3003	GPRC5D/CD3/ BCMA	Innovent	Phase 1/2	r/r MM	2024-09-10
MBS314	GPRC5D/CD3/ BCMA	Mabworks Biotechnology Co.,Ltd	Phase 1/2	r/r MM	2024-02-02
SIM0500	GPRC5D/CD3/ BCMA	Simcere	Phase 1	r/r MM	2024-05-10

Note: r/r MM: Relapsed or refractory multiple myeloma

As of Mya 9th 2025

Source: CDE, Frost & Sullivan Analysis

Competitive Landscape of Global GPRC5D/CD3/BCMA Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
IBI3003	GPRC5D/CD3/BCMA	Innovent Biologics Co. Ltd.	Phase 1/2	r/r MM	2023-10-13
MBS314	GPRC5D/CD3/BCMA	Mabworks Biotech Co., Ltd.	Phase 1/2	r/r MM	2024-01-30
JNJ-79635322	GPRC5D/CD3/BCMA	Janssen	Phase 1	r/r MM	2022-12-15
SIM0500	GPRC5D/CD3/BCMA	Simcere Pharmaceutical Co., Ltd.	Phase 1	r/r MM	2024-04-19

Note: r/r MM: Relapsed or refractory multiple myeloma

As of Mya 9th 2025

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Overview of TIM-3

1 *Overview of* TIM *Family*

The T-cell immunoglobulin and mucin-domain containing (TIM) family consists of several proteins that play crucial roles in regulating immune responses.
TIM-3 serves as an inhibitory receptor and plays a vital role in maintaining immune homeostasis by:

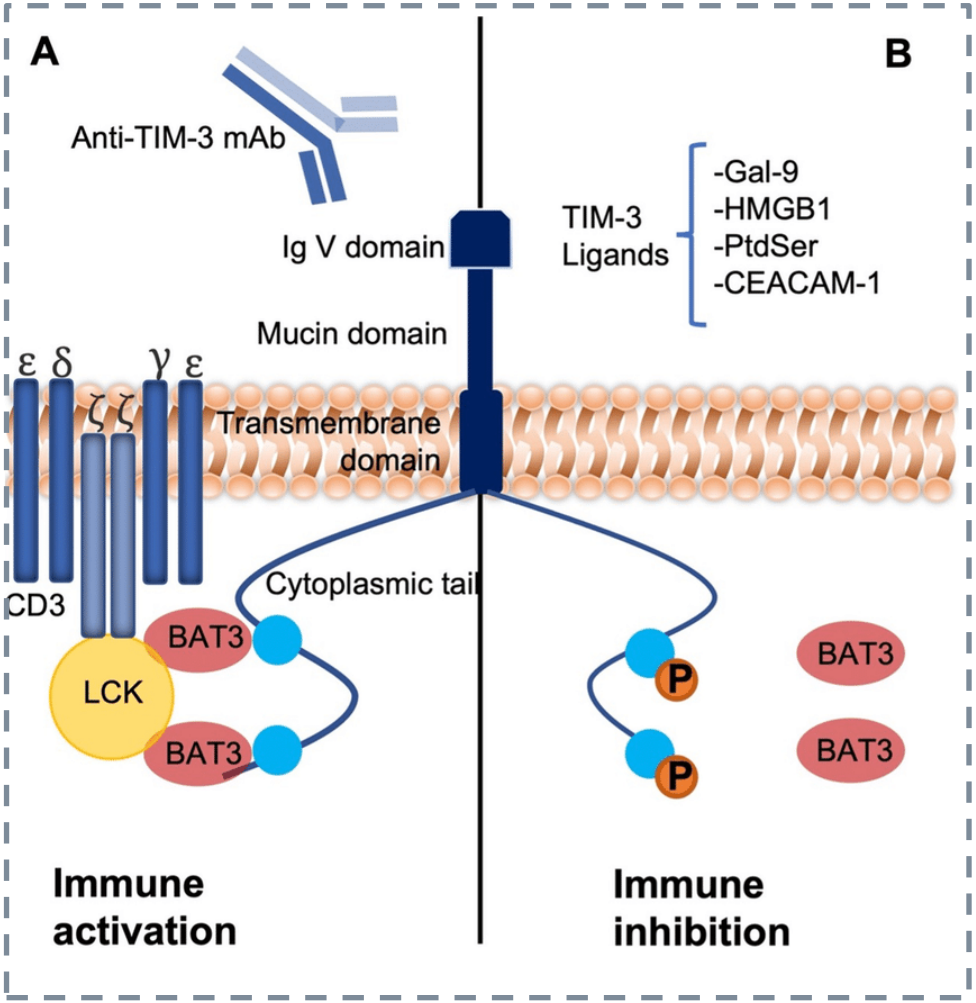
- Regulating T cell exhaustion during chronic infections and cancer.
- Modulating innate immunity through its interaction with ligands like galectin-9, phosphatidylserine, and HMGB1.

2 TIM-3 *in Tumor*

TIM-3 is prominently expressed on specific subsets of T cells in the tumor microenvironment (TME), particularly:

- CD8+ Tumor-Infiltrating Lymphocytes (TILs): TIM-3 expression on these cells is associated with an exhausted phenotype, characterized by reduced proliferative capacity, impaired cytokine production, and decreased cytotoxic activity. The upregulation of TIM-3 is often observed in response to persistent antigenic stimulation, such as in chronic viral infections and cancer.

- CD4+ Regulatory T Cells (Tregs): In cancers, Tregs expressing TIM-3 contribute to immune suppression and tumor tolerance. These cells help in maintaining an immunosuppressive environment by inhibiting effector T cell functions and promoting tumor growth.



Source: Literature Review, Frost & Sullivan Analysis

Competitive Landscape of China anti-TIM-3 Monoclonal Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
Sabatolimab/ MBG453	TIM-3	Novartis	Phase 3	MDS, CML	2020-09-07
TQB2618	TIM-3	Chia Tai-tianqing Pharmaceutical Co., Ltd.	Phase 2	Recurrent and Metastastic NPC	2024-01-15
BC3402	TIM-3	BioCity Biopharma	Phase 1/2	Advanced HCC	2023-09-28
LBL-003	TIM-3	Leads Biolabs Co., Ltd.	Phase 1	Advanced Solid Tumor	2021-09-27
SHR-1702	TIM-3	Hengrui Medicine Co.,Ltd.	Phase 1	MDS, AML	2020-08-17

Note: MDS: Myelodysplastic syndromes; CML: Chronic myelomonocytic leukemia; NPC: Nasopharyngeal cancer; HCC: Hepatocellular carcinoma; AML: Acute myeloid leukemia

As of Mya 9th 2025

Source: CDE, Frost & Sullivan Analysis

Competitive Landscape of Global anti-TIM-3 Monoclonal Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
Sabatolimab/ MBG453	TIM-3	Novartis	Phase 3	MDS, CML	2020-02-12
Cobolimab	TIM-3	GlaxoSmithKline	Phase 2/3	NSCLC	2020-12-07
INCAGN02390	TIM-3	Incyte Corporation	Phase 2	Endometrial Cancer	2020-07-09
			Phase 2	HNC	2022-03-18
			Phase 2	Merkel Cell Carcinoma	2023-09-28
TQB2618	TIM-3	Chia Tai Tianqing Pharmaceutical Group Co., Ltd.	Phase 2	NPC	2022-10-03
BGB-A425	TIM-3	BeiGene	Phase 2	HNSCC	2023-06-18
BC3402	TIM-3	Biocity Biopharmaceutics Co., Ltd.	Phase 1/2	HCC	2023-11-01
Sym023	TIM-3	Symphogen A/S	Phase 1/2	NSCLC	2023-12-08
KK2845	TIM-3	Kyowa Kirin Co., Ltd.	Phase 1	Relapsed or Refractory Acute Myeloid Leukemia	2025-02-06
LY3321367	TIM-3	Eli Lilly	Phase 1	Advanced Solid Tumor	2017-04-04
SHR-1702	TIM-3	Hengrui Medicine Co., Ltd.	Phase 1	AML, MDS	2020-06-23
LBL-003	TIM-3	Leads Biolabs Co., Ltd	Phase 1	Advanced Solid Tumor	2021-09-13
NB002	TIM-3	Neologics Bioscience Co., Ltd.	Phase 1	Advanced Solid Tumor	2023-06-29

Note: MDS: Myelodysplastic syndromes; CML: Chronic myelomonocytic leukemia; NSCLC: Non-small cell lung cancer; HNC: Head and neck cancer; NPC: Nasopharyngeal cancer; HNSCC: Head and neck squamous cell carcinoma; HCC: Hepatocellular carcinoma; AML: Acute myeloid leukemia

As of Mya 9th 2025

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Overview of TGFβR2

1 *Overview of* TGF-β *Superfamily*

The Transforming Growth Factor-β (TGF-β) superfamily comprises a large group of cytokines that regulate various cellular processes, including proliferation, differentiation, migration, and apoptosis.

This superfamily includes:

- TGF-βs: Including TGF-β1, TGF-β2, and TGF-β3.
- Bone Morphogenetic Proteins (BMPs): Involved in bone and cartilage development.
- Growth and Differentiation Factors (GDFs): Important for cell differentiation.
- Activins and Inhibins: Regulate reproductive processes.

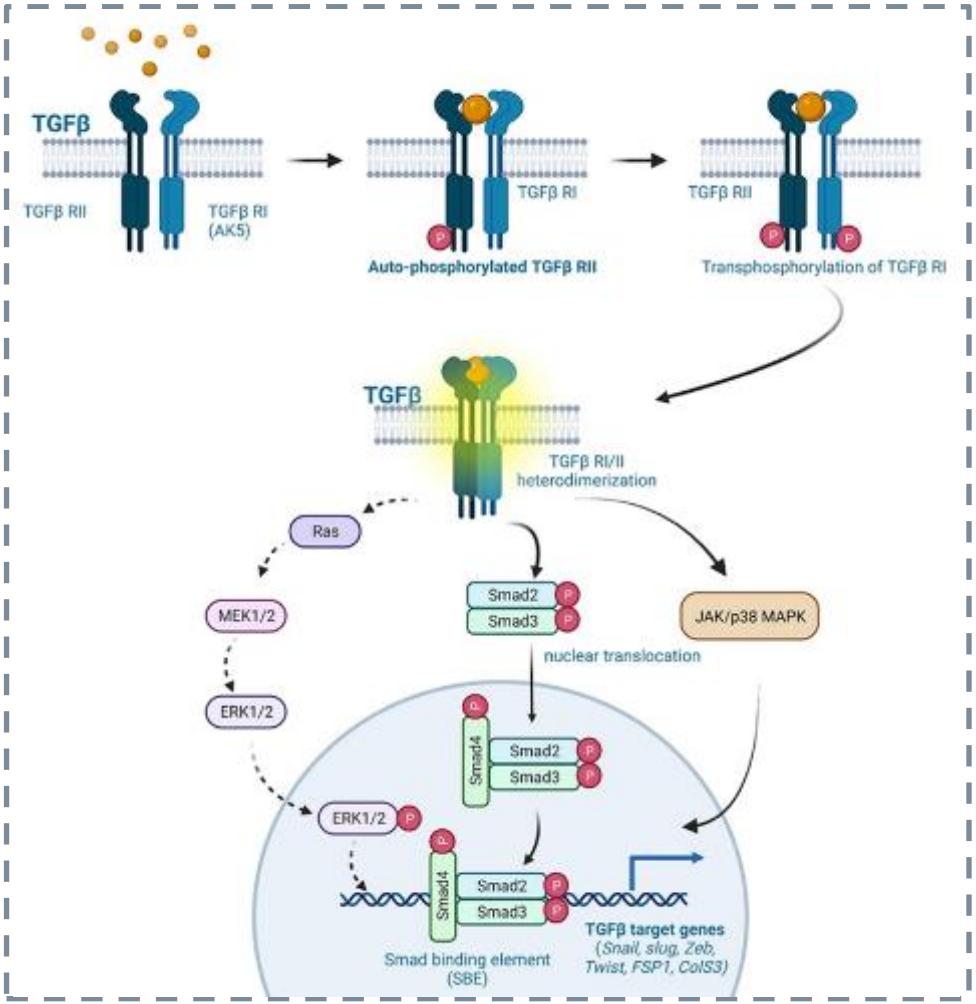
2 TGFβR2 *Signaling Pathway*

TGFβR2 is a serine/threonine kinase receptor that forms a part of the TGF-β receptor complex. It has:

- An extracellular ligand-binding domain.
- A single transmembrane domain.
- An intracellular serine/threonine kinase domain.

TGF-β signaling has a dual role in cancer:

- **Tumor Suppression**: In normal and early-stage cancer cells, TGF-β signaling inhibits cell proliferation and induces apoptosis.
- **Tumor Promotion**: In advanced cancers, cells often develop resistance to TGF-β's suppressive effects. TGF-β signaling can then promote tumor progression, invasion, and metastasis by inducing epithelial-mesenchymal transition (EMT), enhancing cell migration, and modulating the tumor microenvironment.



Source: Literature Review, Frost & Sullivan Analysis

Competitive Landscape of China PD-(L)1/TGFβ(R) Antibody Fusion Protein Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
SHR-1701	PD-L1/TGFβR	Hengrui Medicine Co.,Ltd.	Phase 3	GC and GEJ Cancer	2021-11-24
		Hengrui Medicine Co.,Ltd.	Phase 3	Recurrent and Metastatic Cervical Cancer	2021-11-22
		Hengrui Medicine Co.,Ltd.	Phase 3	NSCLC	2021-11-17
TQB2868	PD-1/TGFβ	Chia Tai Tianqing Pharmaceutical Group Co., Ltd.	Phase 2	Pancreatic Cancer	2024-03-05
			Phase 1/2	Advanced HCC	2023-02-27
LBL-015	PD-1/TGFβR	Leads Biolabs Co., Ltd.	Phase 1/2	Advanced Solid Tumor	2021-09-22
6MW3511	PD-L1/TGFβR	Mabwell Bioscience Co., Ltd.	Phase 1/2	Advanced Solid Tumor	2022-09-01
HB0028	PD-L1/TGFβ	Huabo Biopharm Co., Ltd.	Phase 1/2	Advanced Solid Tumor	2022-08-09
PM8001	PD-L1/TGFβ	Biotheus Inc.	Phase 1/2	Advanced Solid Tumor	2020-06-24
LY01019	PD-L1/TGFβ	Boan Biotechnology Co. Ltd.	Phase 1	Advanced Solid Tumor	2022-08-30
BJ-005	PD-L1/TGFβR	BJ Bioscience Inc	Phase 1	Advanced Solid Tumor	2022-03-09
QLS31901	PD-L1/TGFβ	Qilu Pharmaceutical Co.,Ltd	Phase 1	Advanced Solid Tumor	2021-06-02
TST005	PD-L1/TGFβ	Transcenta Therapeutics	Phase 1	Advanced Solid Tumor	2022-07-01
JS201	PD-1/TGFβ	Junshi Biosciences Co.,Ltd.	Phase 1	Advanced Solid Tumor	2021-05-21

As of Mya 9th 2025

Source: CDE, Frost & Sullivan Analysis

Note: GC: Gastric cancer; GEJ: Gastroesophageal junction; NSCLC: Non-small cell lung cancer; HCC: Hepatocellular carcinoma

Competitive Landscape of Global PD-(L)1/TGFβ(R) Antibody Fusion Protein Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
SHR-1701	PD-L1/TGFβR	Hengrui Medicine Co.,Ltd.	Phase 3	Gastric Cancer or Gastroesophageal Junction Cancer	2021-07-06
			Phase 3	Non-squamous NSCLC	2021-11-24
			Phase 3	Cervical Cancer	2022-01-05
JS201	PD-1/TGFβ	Junshi Biosciences Co.,Ltd.	Phase 2	Advanced SCLC	2021-07-07
TQB2868	PD-1/TGFβ	Chia Tai Tianqing Pharmaceutical Group Co., Ltd.	Phase 2	Advanced HCC	2024-06-04
LBL-015	PD-1/TGFβR	Leads Biolabs Co., Ltd.	Phase 1/2	Advanced Solid Tumor	2021-11-04
6MW3511	PD-L1/TGFβR	Mabwell Bioscience Co., Ltd.	Phase 1/2	Solid Tumor	2022-09-01
HB0028	PD-L1/TGFβ	Huabo Biopharm Co., Ltd.	Phase 1/2	Advanced Solid Tumor	2024-01-25
QLS31901	PD-L1/TGFβ	Qilu Pharmaceutical Co., Ltd.	Phase 1	Advanced Solid Tumor	2021-07-08
BJ-005	PD-L1/TGFβR	BJ Bioscience, Inc.	Phase 1	Advanced Solid Tumor or Lymphoma	2021-11-10
PM8001	PD-L1/TGFβ	Biotheus Inc.	Phase 1	Advanced Solid Tumor	2022-09-13

Note: GC: Gastric cancer; GEJ: Gastroesophageal junction; NSCLC: Non-small cell lung cancer; HCC: Hepatocellular carcinoma; SCLC: Small cell lung cancer

As of Mya 9th 2025

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Overview of TNFR2

1 *Overview of* TNFR *Superfamily*

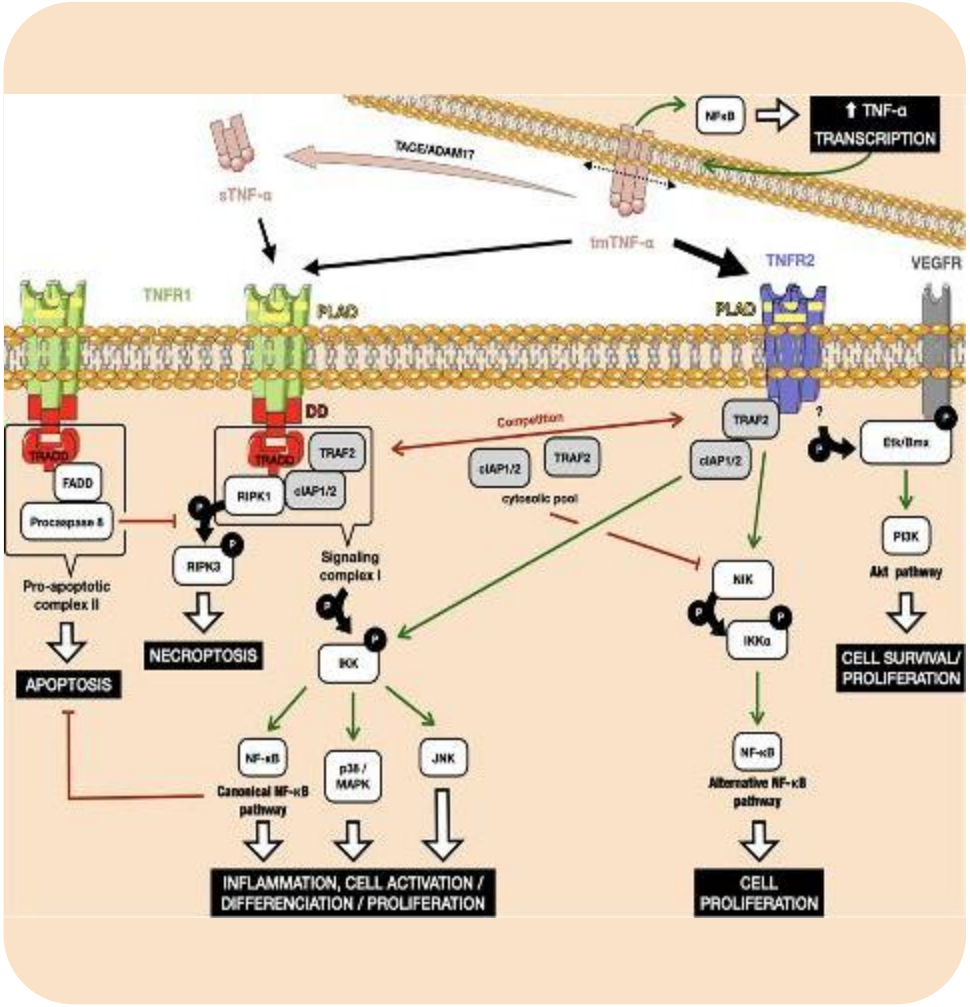
Tumor Necrosis Factor Receptor Superfamily
The Tumor Necrosis Factor Receptor (TNFR) superfamily is a group of receptors that play pivotal roles in regulating immune responses, inflammation, cell proliferation, differentiation, and apoptosis. The superfamily includes:

- **TNFR1:** Primarily mediates inflammatory and apoptotic responses.
- **TNFR2:** Involved in immune modulation and cell survival.

2 TNFR2 *Signaling Pathway*

TNFR2 plays a complex role in cancer biology, functioning both as a potential tumor promoter and as a target for cancer therapy.

- **Tumor Promotion:** TNFR2 is often overexpressed in various tumors and is associated with tumor progression, angiogenesis, and metastasis. It contributes to creating an immunosuppressive tumor microenvironment by promoting the expansion and function of regulatory T cells (Tregs) and myeloid-derived suppressor cells (MDSCs).
- **Therapeutic Target:** Due to its role in immune modulation and tumor growth, TNFR2 is considered a promising target for cancer therapy. Strategies include:
- Monoclonal Antibodies: Antibodies targeting TNFR2 can block its interaction with TNF-α, inhibiting its pro-tumorigenic effects.
- **TNFR2 Agonists:** In some contexts, agonists may be used to selectively stimulate TNFR2 on immune cells to boost anti-tumor immunity.



Source: Literature Review, Frost & Sullivan Analysis

Competitive Landscape of China anti-TNFR2 Monoclonal Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
LBL-019	TNFR2	Leads Biolabs Co., Ltd.	Phase 1/2	Advanced Solid Tumor	2022-02-10
HFB200301	TNFR2	HiFiBiO Therapeutics	Phase 1	GC, RCC, Cutaneous Melanoma, Testicular Cancer, Soft Tissue Sarcoma	2024-02-02
NBL-020	TNFR2	Novarock Biotherapeutics	Phase 1	Advanced Solid Tumor	2023-06-07
SIM0235/ SIM1811-03	TNFR2	Simcere Pharmaceutical	Phase 1	Advanced Solid Tumor, Cutaneous T-cell lymphoma	2022-03-17

Note: GC: Gastric cancer; RCC: Renal cell carcinoma

As of Mya 9th 2025

Source: CDE, Frost & Sullivan Analysis

Competitive Landscape of Global anti-TNFR2 Monoclonal Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
BI-1808	TNFR2	BioInvent International	Phase 1/2	Advanced Solid Tumor	2021-02-12
LBL-019	TNFR2	Leads Biolabs Co.,Ltd	Phase 1/2	Advanced Solid Tumor	2022-02-03
BI-1910	TNFR2	BioInvent International	Phase 1/2	NSCLC, HCC and Other Solid Tumor	2024-01-16
HFB200301	TNFR2	HiFiBiO Therapeutics	Phase 1	GC, RCC, Melanoma, Sarcoma, Testicular Cancer, Cervical Cancer, Mesothelioma, NSCLC, HNSCC	2022-02-14
SIM0235	TNFR2	Simcere Pharmaceutical Co., Ltd.	Phase 1	Advanced Solid Tumor, Cutaneous T-cell Lymphoma	2022-10-06
NBL-020	TNFR2	NovaRock Biotherapeutics, Ltd	Phase 1	Advanced Solid Tumor	2023-05-26
BITR2101	TNFR2	Boston Immune Technologies and Therapeutics	Phase 1	NHL, Cutaneous T Cell Lymphoma, Peripheral T-cell Lymphoma	2024-04-26

Note: NSCLC: Non-small cell lung cancer; HCC: Hepatocellular carcinoma; GC: Gastric cancer; RCC: Renal cell carcinoma; HNSCC: Head and neck squamous cell carcinoma

As of Mya 9th 2025

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Competitive Landscape of China Anti-GDF15 Monoclonal Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
Ponsegromab	GDF15	Pfizer	Phase 2	Cachexia	2023-02-27
			Phase 2	Heart Failure	2023-03-02

As of Mya 9th 2025

Source: CDE, Frost & Sullivan Analysis

Competitive Landscape of Global Anti-GDF15 Monoclonal Antibody Pipeline

Drug Name	Target	Company	Clinical Stage	Indication	First Posted Date
Ponsegromab	GDF15	Pfizer	Phase 2	Cachexia and Advanced Solid Tumor	2022-09-19
			Phase 2	Heart Failure	2022-08-08
CTL-002	GDF15	CatalYm GmbH	Phase 2	Muscle Invasive Bladder	2023-09-28
AV-380	GDF15	AVEO Pharmaceuticals, Inc.	Phase 1	Cachexia	2023-05-19

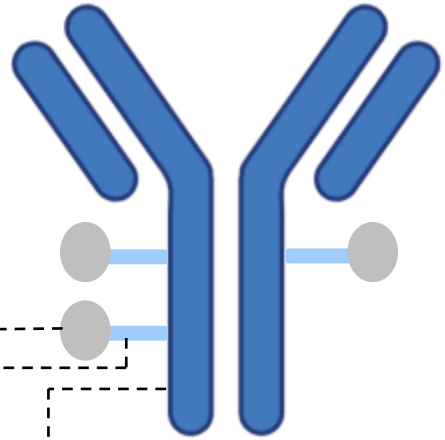
As of Mya 9th 2025

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Overview of Antibody-Drug Conjugate (ADC) Therapy

- ADCs are complex molecules composed of an antibody linked to a biologically active (anticancer) agent. ADC targets a specific antigen only found on target cells. Once it binds to the cell, it triggers internalization of the antibody, together with the drug, thus killing the cancer cell. This maximizes efficacy and minimizes systemic exposure. The main structure and mechanism of action of ADC are elaborated below.

Main Structure of ADC

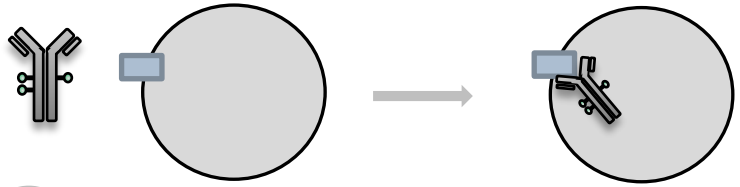


Antibody — Specific for a tumor-associated antigen that has restricted expression on normal cells

Linker — Attaches the cytotoxic agent to the antibody

Drug — Designed to kill target cells when internalized and released

Mechanism of Action of ADC



1. ADC binds to an receptor on the surface of cancer cells and the ADC-receptor complex is internalized.

2. The active cytotoxic agent is detached from the antibody and released within the cancer cell.

3. The cancer cell is killed by the cytotoxic agent and undergoes apoptosis

Source: Frost & Sullivan Analysis

Advantages of ADCs

Antibody

Pros

- **Targeting Specificity:** Antibodies can find specific antigens on cancer cells (extracellular) or other specific antigens on other cells which may interrupt cancer growth signaling pathway.

Cons

- **Insufficient Cytotoxicity:** Antibodies don't kill cancer cells directly, it may not be very effective in destroying cancer cells.
- **Limitation in Certain Cancer:** some antibodies may play import roles in other healthy cells, which may cause side effects.
- **Drug Resistance**

Chemotherapy

Pros

- **Toxicity:** Chemotherapies damage nucleus of cells when they divide, that say, chemotherapies destroy cancer cells directly.

Cons

- **Whole body cytotoxicity**: Chemotherapy circulates throughout patients' body in the blood stream, it also destroy healthy cells and tissue, which cause off-target cytotoxicity that may worsen patients' quality of life.
- **Limitation in Drug Selection:** Some potent cytotoxic agents may not be prescribed to patients due to the concerns for the damage it may bring to healthy cells.
- **Drug Resistance**

Small Molecules Inhibitors

Pros

- **Targeting Specificity:** Small molecule inhibitors usually targeting enzyme in the cancer cells (intracellular) to block certain pathway, and eventually interrupt with cancer growing.

Cons

- **Off-target cytotoxicity**: The target specificity is not as specific as antibodies, enzyme inhibitors may affect multiple biochemical reactions in healthy cells.
- **Drug Resistance**

Combining the Major Advantages in ADC Development

ADC

- **Targeting Specificity**: Antibody section provides cancer specific targeting, which direct the ADC drug to the cancer cells accurately.
- **Cytotoxicity:** Chemical drug payload provides sufficient cytotoxicity to destroy cancer cells. And due to its cancer cell targeting feature, ADC drug can treat patients with a higher dosage.
- **Drug Resistance Overcome:** Optimized ADC combination of mAbs and payloads may help to reduce, or even overcome drug resistance.
- **Penetrating Greater Patients Pool:** By exploring more cancer specific antibodies and novel chemical drugs with greater cytotoxicity, novel ADCs can be developed, which makes it possible for patients who can't be treated by the current approaches to get treated with novel ADCs, more cancer indications will be included in the ADC portfolio.
- **Example:** Kadcyla (ado-trastuzumab emtansine) is a ADC drug that combines HER2 specific antibody trastuzumab with a cytotoxin DM1, its antibody segments can deliver the DM1 payload to HER2 expressing breast cancer cells accurately, and it has showed potent efficacy in clinical practice.

Source: Frost & Sullivan Analysis

Key Elements of ADCs Agent

- To develop a successful ADCs agent, four key elements should be put into consideration, including tumor antigen, antibody, linker, and cytotoxic drug.

Element	Description
Tumor Antigen	• ADCs agents are mainly used for anti-tumor effects. An ideal target antigen should be overexpressed on the surface of tumor cells, but has little or none of expression in normal tissues. • When the tumor antigen is bound by the antibody of the ADCs agent, they can be effectively internalized and the cytotoxic drug can be released within the tumor cells.
Antibody	• Specificity, affinity and pharmacokinetics are important indexes to characterize an antibody. • The high affinity of antibody to tumor antigen is considered to be the core of killing target cells. Generally, the binding affinity index $K_D < 10^{-3}$ M is the basic requirement for the antibody. Based on the high affinity, the antibody is expected to have low immunogenicity, a long half-life, and to be stable in the blood.
Linker	• An ideal linker should maintain stability in the blood while effectively release the drug in target cells. In addition, linkers can be modified to be appropriate for different modes of metabolism or activation. • There are two types of linkers: cleavable linkers and non-cleavable linkers. The greatest advantage of non-cleavable linkers compared to cleavable linkers is their increased plasma stability, which offers reduced off-target toxicity. However, cleavable linkers can maintain better potency by allowing a faster rate of activation and release of the cytotoxic drugs.
Cytotoxic Drug	• The percent of an injected antibody that localize to a tumor is very small (0.003-0.08% injected does per gram of tumor). For this reason, it is necessary to use cytotoxic drug of high efficiency and high sensitivity (free drug IC_{50}: 10^{-11}-10^{-9} M) of killing target cells. • There are two common categories of drugs used for ADCs: microtubule inhibitors and DNA-damaging agents.

Source: Frost & Sullivan Analysis

Key Technical Barriers of ADC Therapy

- Critical to the clinical efficacy of an ADC are the target site-specificity and binding properties of the antibody, the in vitro and in vivo stability of the linker and drug species, the potency of the drug and both the distribution and average number of drug species on the antibody. Therefore, in ADC therapy development, the selection of targeted antigen, chemical linker, the drug and the choice of attachment sites are the key technical barriers and areas of improvement to reduce adverse events.

ADC Technical Barriers

Linker Stability

- Linker stability engineering is a key challenge since linkers may break and release drug prematurely, killing normal cells.
- Conventional bioconjugation chemistries suffer from premature loss of payload cargo in the bloodstream, which translates to loss of efficacy and off-site toxicity.

Drug Selection

- Drug selection is a technical challenge as it can affect internalization, ADC polarity and immunogenicity, and therapeutic efficacy.
- The selected drug needs to have the following characteristics: high cytotoxicity, affinity, low hydrophobicity and sensitivity. This makes few molecules suitable as the drug. Currently, most molecules derivatives from the auristatins and maytansinoids families.

Optimal DAR

- DAR is critical in determining efficacy, but designing ADCs with optimal drug-to-antibody ratio (DAR) is a key technical barrier.
- DAR varies within a single product and controlling this heterogeneity is difficult.
- Low DAR may not provide an adequate cytotoxic response while high DAR can become unstable and cause increased aggregation.

Antigen Selection and Antibody Reconstruction

- Selection of targeted antigen is a technical barrier. Challenges include low expression and low rate of internalization of the complex.
- IgG reconstruction is a key technical barrier in order to connect to linker with the drug and have high homogeneity. In conventional ADC therapy, TDC (THIOMAB drug conjugates) technique is adopted but has risk for dissociation in bloodstream.

Source: Frost & Sullivan Analysis

Four Generations of ADC Structure

Generations	Conjugations	Linker	Payload	Limitations
1st generation (e.g. *Mylotarg 2010*)	Random lysines	Unstable	Low potency; e.g., conventional chemotherapy	Heterogeneity; lack of efficacy; systemic toxicity due to premature drug loss; highly immunogenic
2nd generation (e.g. *Adcetris* 2011; *Kadcyla* 2013)	Random lysines; Reduced interchain cysteines	Improved stability; cleavable vs. noncleavable	~1000x more potent than chemo; antimicrotubule MOA; only active against proliferating cells	Heterogeneity; fast clearance for high DARs; premature drug loss; narrow TI; drug resistance
3rd generation	Site specific adopted; engineered cysteins (e.g., THIOMAB); novel constructs	Stable in circulation; finetuned to match drug; release drugs in tumors	Highly potent; also DNA damaging MOA; target proliferating & non-proliferating cells; against modest target expression	Possible toxicity due to highly potent payloads; catabolism may be different across species
4th generation	Site-specific conjugation (e.g., engineered antibodies, enzymatic coupling)	Highly stable and cleavable under specific conditions	Ultra-potent payloads with novel mechanisms (e.g., protein degraders, immune stimulators)	Challenges in patient stratification and biomarker identification; complex manufacturing processes

Source: Frost & Sullivan; Literature Review

Comparisons of Four Generations of ADCs

	1st Generation	2nd Generation	3rd Generation	4th Generation
DAR Featured	Average DAR 3-4	DAR 2 or DAR 4	DAR 8 or more	DAR 7.4-7.8
Antibody Re-engineering	Not required	Required	Not required	Required
Development Time	Few days	Several months	Few days	Few days
Coupling	Heterogenous	Heterogenous	Homogenous	Homogeneous
Plasma Stability	Moderate	Improved	High	Ultra-high stability
Bioconjugation & Reproducibility	Ease of bioconjugation but lack of reproducibility	Tedious bioconjugation procedures but good reproducibility	Ease of bioconjugation and excellent reproducibility, even at an industrial scale	Advanced bioconjugation techniques ensuring high reproducibility
Therapeutic Index	Narrow	Improved	Further improved	Significantly improved with reduced toxicity

- The limitations and failures of Mylotrag has been avoided by subsequent FDA-approved ADCs, Adcetris and Kadcyla, by using different linkers, with the improvement in cytotoxic payload potency. However, these ADCs generally randomly conjugate cytotoxic drugs to either lysine or cysteine residues of the antibody, which generate heterogeneous ADCs with inconsistent in vivo PK and potentially in therapeutic windows and efficacy profiles due to inconsistent conjugating sites.
- Noteworthy is the vast number of potential conjugation sites for lysine-based conjugation would further influent the property consistency of ADCs. Over years of development of ADCs, issues such as wisely chosen targeted antigens, linker chemistry, cleavage strategy and conjugation site specificity have been hot topics for optimizing the drug therapeutic efficacy while minimizing adverse events.

Source: Frost & Sullivan Analysis

Analysis of Targets for ADC Drugs

- HER2 is still the most popular target in ADC drugs. However, with the ADC drug research and development ushered in a new round of upsurge, the target selection showed a rapid diversification trend. TROP2 has been another popular target, Claudin 18.2, MUC1 and TF also join in the market. According to the data collected from CDE, 23 targets have been set up in the domestic ADC drug field, and a total of 67 ADC drug products are under research (of which 40 ADC drugs have entered clinical trials).

Target	Information	Project - Phase
HER2	Receptor tyrosine-protein kinase, controls cell growth and repair	Vidicizumab - Approved TAA013 - Phase 3 SHR-A1811 - Phase 2 ARX788 - Phase 2 A166 - Phase 2 MRG002 - Phase 2 DP303c - Phase 2
Trop2	Trop2 is another popular development target in ADC field after HER2. Trop2 is a single transmembrane glycoprotein highly expressed in a variety of tumors. Targeting trop2 can significantly inhibit the growth of a variety of tumor cells.	Trodelvy - FDA approved (preclinical in China)
Claudin 18.2	It is a four transmembrane protein, highly specific in gastric cancer, pancreatic cancer and other tumors.	CMG901 - Phase I SYS1801 - Approved by FDA with identification of orphan medicine.
MUC1	It is a highly glycosylated transmembrane protein, which is overexpressed in tumors including breast cancer, ovarian cancer, pancreatic cancer and colon cancer.	Tub201 - Preclinical experiments application submitted
TF	TF is a protein involved in tumor signal transduction and angiogenesis. It is overexpressed in the vast majority of patients with cervical cancer and many other solid tumors, including ovarian, lung, pancreas, colorectal and head and neck cancers	Tisotumab Vedotin - FDA is assessing MRG004A - Preclinical experiments application submitted

Source: Frost & Sullivan Analysis

Analysis of the Advantages of the Main Toxins of ADC Drugs

Microtubule/tubulin inhibitors can be classified into two major categories according to their mechanisms of action: agents promoting tubulin polymerization and stabilizing microtubule structures (e.g., paclitaxel, epothilones, discodermolide and taccalonolides), and agents inhibiting tubulin polymerization and destabilizing microtubule structures (such as maytansinoids, auristatins, vinblastine and vincristine).

Toxins	Mechanism	Advantages	Disadvantages
Maytansinoids	Maytansinoids are anti-mitotic tubulin inhibitors derived from maytansine. Maytansine and maytansinoids bind to the maytansine site, resulting in the suppression of microtubule dynamics and causes cell cycle arrest in the G2/M phase.	Maytansinoid, which demonstrates increased plasma stability, greater therapeutic window, and reduced off-target toxicity compared to that with cleavable linkers	Due to the structural complexity including numerous stereocenters, the total synthesis of maytansine and its analogues is cost prohibitive even if it were
Auristatins	Auristatins are derived from the natural product dolastatin-10. Dolastatin-10 and its analogs inhibit tubulin-dependent GTP binding and block the binding of vinca alkaloids to tubulin in a noncompetitive manner.	Both MMAE and MMAF showed no degradation in plasma, in human liver lysosomal environment, or by the action of proteases. As free toxins, the cytotoxicities of MMAE and MMAF are less potent than that of dolastatin 10 in lymphoma cells in vitro.	
Cryptophycins	The cryptophycins are a family of 16-membered cyclic depsipeptides, first isolated from terrestrial blue-green algae. The most abundant component, cryptophycin-1 (10) (Figure 5), has demonstrated excellent activity against a broad spectrum of solid tumors with IC50 values in the picomolar range [96].	it was not substrate for the P-gp in multiple-drug resistant (MDR) cancer cell lines significantly.	However, the intrinsically low bioavailability of cryptophycin-1 caused by its instability and solubility rendered it ineffificacious in vivo.

Source: Frost & Sullivan Analysis

Analysis of the advantages and disadvantages of the main linker technology of ADC drugs

- A linker selected must be stable and efficient to release the cytotoxic agent upon internalization of ADC. Linkers for ADCs are categorized into cleavable linkers and non-cleavable linkers. Non-cleavable ones require lysosomal degradation of antibody for releasing cytotoxic agent.
- ADCs with cleavable linkers have broader efficacy and faster rates of activating and releasing cytotoxic drugs for most cell lines. On the contrast, ADCs with non-cleavable linkers can possibly provide increased plasma stability, greater therapeutic window, and reduced off-target toxicity. To reduce aggregation and improve the solubility of some ADCs, hydrophilic linkers such as β-glucuronide linker, Sulfo-SPDB, and Mal-PEG4-NHS were investigated. In conclusion, each type of linker has advantages and disadvantages, and each can be modified to achieve a fine balance between target efficacies and undesired toxicities.

Linker	Linker Type	Pros	Cons
MHH	Chemical labile (acid labile) linker	Cleaving in acidic environment	Poor stability
DSDM	Disulfide-containing reducible linker	Intracelluar release of payload	Potential premature cleavage during circulation
Sulfo-SPDB	Disulfide-containing reducible linker	Intracelluar release of payload	Potential premature cleavage during circulation
MC-VC-PABC	Enzymatically cleavable linker	Stability during circulation	Hydrophobicity
SMCC	Non-cleavable bifunctional linker	Stability during circulation	No “bystander effect”
Mal-PEG-NHS	Non-cleavable spacer linker	Improve water solubility and reduce plasma clearance	No “bystander effect”
GBC	Enzyme-labile beta-Glucuronide linker	Defined DAR hemogeneity	Requires multiple steps

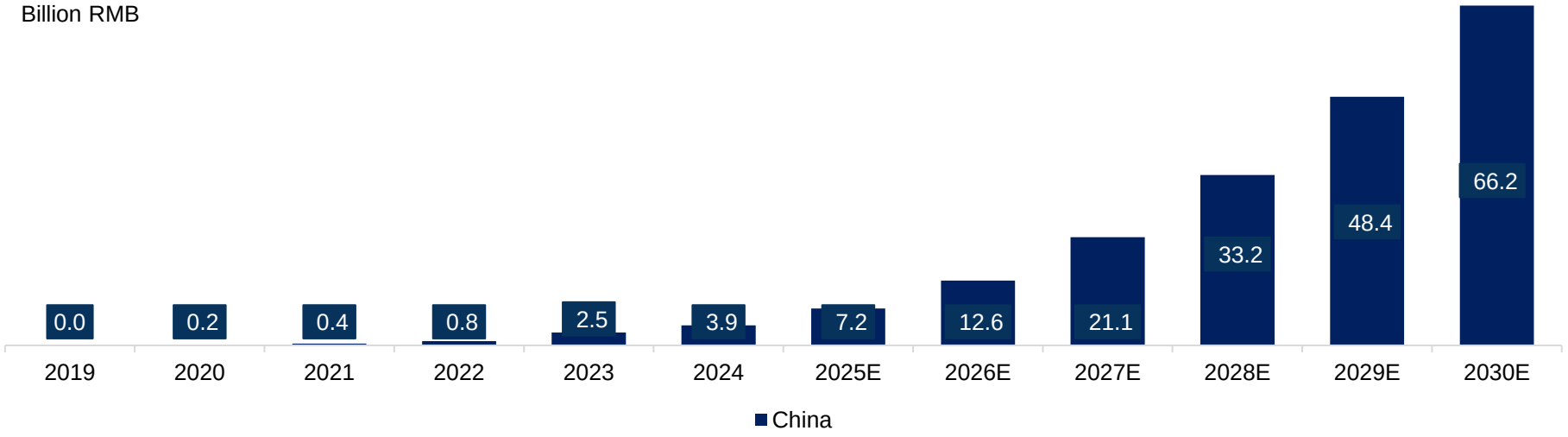
Source: Frost & Sullivan Analysis, literature review

Historical and Forecasted of Global ADC Drug Market Size by Region, 2019-2030E

- China's ADC drug market size reached RMB3.9 billion in 2024, with a CAGR of 89.3% from 2020 to 2024. The market size will climb to RMB21.1 billion and RMB66.2 billion in 2027 and 2030 respectively.

Historical and Forecasted of Global ADC Drug Market Size by Region, 2019-2030E

CAGR	China
2019-2024	89.3% (2020-2024)
2024-2027E	75.1%
2027E-2030E	46.4%



Source: Frost & Sullivan Analysis

Growth Drivers of ADCs Drug Market

Increase of Addressable Patient Number	• ADCs are one of the fastest growing drug classes in oncology in recent years, having undergone three generations of revolutionary changes in terms of both precision targeting and efficient killing. The existing indications for ADC drugs are mainly in breast cancer, ovarian cancer, non-Hodgkin's lymphoma and non-small cell lung cancer, all of which are showing a increasing incidence worldwide and are in urgent need of more effective treatment options. Increasingly addressable patient number will significantly expend the ADCs market size.
Capital Support	• The currently marketed ADC drugs are performing well, with a global market size of over US$4 billion by 2020. At the same time the funding and deal partnering frenzy in the sector has also reached a crescendo. RemeGen's US$2.6 billion deal set a new record for innovative drug license out in China. Dozens of innovative drugs in pre-clinical and clinical development are injecting new hope into the development of the ADCs drug market, a situation that is bound to attract more funding. For example, in February 2022, Johnson and Eli Lilly entered into an antibody-coupled drug partnership with Mersana and ImmunoGen respectively, both of which will invest more than US$1 billion in the ADC track, giving them strong financial backing for growth.
Favorable Policy	• Chinese policy environment of encouraging innovation and accelerating the introduction of clinically-needed drugs is a good guarantee for the rapid development of ADC drugs. Although domestic pharmaceutical companies are still in their infancy in ADC drug development, the strong momentum of the leading companies, supported by health insurance reform, accelerated drug trials, increased investment in R&D by pharmaceutical companies and continued improvement in patients' affordability of drugs, will certainly continue to drive sustained innovation of the whole market.

Source: Literature Review, Frost & Sullivan analysis

Future Trends of ADCs Drug Market (1)

Better Linkers and Toxins	• Nowadays, research on novel targets and toxic small molecules, better linker design and homogenisation of drug-antibody coupling ratios is continuously emerging. New targeted coupling technologies are able to combine genetic engineering technologies to add to the homogeneity and pharmacokinetic profile of ADCs through various approaches, for instance, the introduction of unnatural amino acids, the application of multiple enzymatic reactions, and disulfide bond modification, in the meantime reducing the toxic side effects of the drug. Optimization of ADC drugs will definitely attract more attention, with more positive data and superior clinical progress in the current pipeline to look forward to.
Increase of Targets	• Up to now, ADC targets have been most extensively studied for HER-2, and the development of differentiated targets, including B7-H3, CD138 and LIV1, has never stopped, which is expected to expand the scope of ADC applications, making it a new type of highly effective and low-toxicity antibody drug for the treatment of multiple tumour types. Besides, a number of studies have shown that ADC drugs have synergistic effects in combination with other therapies, offering hope to a large number of potential patients who are not well benefitted by conventional therapies and monotherapy, and warranting further exploration for greater clinical value.
Expanding Indications to Non-oncology Field	• The diversification of the action forms of antibody-coupled drugs resulting from technological maturity will eventually lead the market to develop towards broader potential targets and indications range, particularly in non-oncology areas such as eye diseases and autoimmune diseases. It is also expected to expand into the early stages of cancer with a larger patient population and meet greater clinical demand.

Source: Literature Review, FDA, Frost & Sullivan analysis

Future Trends of ADCs Drug Market (2)

Mitigating Toxicity

- The current clinical use of ADCs is associated with safety concerns. Most marketed ADCs receive boxed warnings from the FDA for severe or life-threatening neutropenia, hepatotoxicity, cardiac toxicity, embryofetal toxicity and severe diarrhea. In addition, other adverse reactions, such as hypersensitivity reactions, infusion-related reactions, and acute kidney injury, were found.
- Further studies are expected to improve ADC safety and reduce toxicity to increase the number of addressable patients.

Combo Use

- Clinical results demonstrated that the ADCs combo with IO therapy achieves encouraging therapeutic effects. On the one hand, ADCs directly activate DCs to mediate the recruitment and activation of effector T cells; on the other hand, ADCs induce immunogenic cell death of tumor cells to enhance the immune response.
- In the future, ADC-IO combination therapy has the potential to become a new combination form for ineffective tumor immunotherapy.

Source: Literature Review, FDA, Frost & Sullivan analysis

Appendix

- The company has obtained the IND approval from the CDE to initiate a single-arm pivotal trial in China to evaluate LBL-024 for the third-line (3L) treatment for EP-NEC in April 2024. Therefore, LBL-024 is the world's first and only 4-1BB-targeted immunotherapy to have reached pivotal trial stage.
- The binding affinity of LBL-024 for PD-L1 versus 4-1BB is approximately 300:1, as compared to 0.9:1 of Genmab's acasunlimab, according to publicly available data.
- In April 2024, an application for an End-of-Phase II meeting (related to completion of Phase II clinical trial and initiation of a pivotal trial) for LBL-007 in combination with tislelizumab for the 1L treatment of NPC was submitted to the CDE of the NMPA. Therefore, LBL-007 ranks among the top three LAG3-targeted monoclonal antibodies globally in terms of clinical development stage, to have entered the pivotal stage. LBL-007 is the first in its class with proven efficacy in cancer indications beyond melanoma.
- Four core and key products are positioned to be one of the world's top three clinically advanced candidates.
- LBL-034 is the second most clinically advanced GPRC5D-targeted CD3 T-cell engagers globally.
- For market size forecast, exchange rate of USD:CNY from 2019 to 2022 is 6.9, 6.9, 6.5, 6.7, the rate from 2023 until future keep consistent with 2022.
- The prognosis for SCLC patients is poor, with a median overall survival (mOS) of 15-20 months for limited-stage disease, 8 to 13 months for extensive-stage disease and 4-5 months for relapsed or refractory disease.
- Gemcitabine plus Cisplatin remains the first-line treatment for BTC.
- In 2023, the first full year following its commercial launch, OpdualagTM achieved global sales of US$627 million.
- The global market of T-cell engagers is estimated increase from USD 1.1 billion in 2023 to USD 21.4 billion in 2030 at a CAGR of 53.8%; the China market of T-cell engagers is estimated increase from RMB 0.2 billion in 2023 to RMB 8.3 billion in 2030 at a CAGR of 77.4%.

Source: Literature Review, FDA, Frost & Sullivan analysis

Appendix

- LBL-024 was granted Orphan Drug Designation (ODD) by the FDA for the treatment of advanced NEC.
- LBL-034 was granted Orphan Drug Designation (ODD) by the FDA for the treatment of Multiple Myeloma.
- **Ovarian Cancer**: Maintenance therapy is crucial for controlling disease progression, but the effectiveness of chemotherapy as a maintenance treatment is hard to gauge, and the PFS for patients treated with chemotherapy and bevacizumab is suboptimal. Olaparib, a PARP inhibitor, is recommended as the first-line maintenance treatment for advanced OC patients with BRCA mutations. Moreover, the combination of olaparib with bevacizumab is recommended as the first-line maintenance treatment for patients demonstrating homologous recombination deficiency-positive status. However, like other targeted therapies, PARP inhibitors also face challenges with drug resistance and are specifically effective in patients harboring certain genetic mutations. Additionally, OC patients often experience multiple recurrences, with shorter intervals between each relapse. As the disease progresses and treatment lines advance, drug resistance becomes more common.
- Currently, platinum-based chemotherapy represents the SOC for OC patients. Although OC initially responds well to first-line chemotherapy, most patients eventually develop resistance and relapse.
- **HCC**: Fewer than one-third of patients benefit from sorafenib, and drug resistance typically develops within six months of the initial regimen. Long-term use of sorafenib also presents issues such as toxicity and drug inefficacy. Due to the limited improvement in clinical outcomes with small molecule targeted drugs, PD-1/PD-L1 inhibitors have been introduced to improve outcomes. Despite this, current immuno-oncology therapies still do not provide significant benefits in terms of progression-free and overall survival.

  Around 70% of advanced HCC patients receive the first-line treatment.
- **Cervical cancer**: Approximately 80% of advanced cervical cancer patients receive first-line treatment. Among those who complete this therapy, around 50% proceed to second-line treatment.

Source: Literature Review, FDA, Frost & Sullivan analysis

Appendix

- **NPC:** Around 85% of advanced NPC patients receive the first-line treatment, and 65% of advanced NPC patients receive second-line treatment.
- **CRC:** The efficacy of current treatments remains modest, with the five-year survival rate for late-stage CRC patients being only about 15%.
- **GC:** Gastric cancer treatment strategies vary based on the stage of the disease, with distinct approaches for early and advanced stages. For early-stage gastric cancer, ranging from stage I to stage III, surgery remains the SOC and is often complemented by adjuvant chemotherapy to reduce recurrence risk. Commonly used regimens include combinations of oxaliplatin with fluorouracil (5-FU) or capecitabine, as well as cisplatin-based therapies. In cases of non-metastatic, resectable gastric cancer, neoadjuvant therapy, which involves agents like docetaxel, cisplatin, and 5-FU, is employed to shrink tumors before surgery. However, for unresectable cases, simultaneous radiotherapy and chemotherapy are critical, typically using carboplatin, paclitaxel, or cisplatin-based regimens. For advanced metastatic gastric cancer, usually refers to stage IV, the focus shifts to systemic therapies aimed at prolonging survival and improving quality of life.
- GC: The combination of fluoropyrimidine and platinum compounds is recognized as first-line therapy for unresectable GC populations. Targeted therapies for GC applications, with targets including human epidermal growth factor receptor 2 (HER2), epidermal growth factor receptor (EGFR), and vascular endothelial growth factor (VEGF) and its receptors, which are able to revolutionize treatment and improve prognosis for GC patients. Trastuzumab, a monoclonal antibody against HER2, is added to chemotherapy as standard first-line treatment for HER2-positive advanced GC. Ramucirumab, a monoclonal antibody against VEGFR2, is added to paclitaxel as the second-line treatment for advanced GC. Immunotherapy has become a promising therapy against advanced GC, recommended as the third-line treatment by NCCN and CSCO.

Source: Frost & Sullivan analysis

Appendix

- **GC:** HER2 status plays a pivotal role in guiding treatment decisions. HER2-positive patients typically receive trastuzumab, a HER2-targeting monoclonal antibody, as the foundation of first-line therapy, combined with fluoropyrimidines, such as fluorouracil or capecitabine and platinum agents like cisplatin or oxaliplatin. Second-line therapies for HER2-positive patients often involve trastuzumab with paclitaxel or anthracyclines, while third-line options include PD-1 inhibitors or targeted therapies such as apatinib. For HER2-negative patients, first-line treatment options include fluorouracil-based regimens combined with docetaxel, paclitaxel, or platinum agents, while second-line therapies often involve irinotecan or monotherapy with agents like paclitaxel or docetaxel. Immunotherapy, particularly PD-1/PD-L1 inhibitors like pembrolizumab and nivolumab, has seen increasing use in advanced cases, particularly for microsatellite instability subtypes or PD-L1-positive tumors. Despite advancements, treatment for advanced gastric cancer remains challenging, with limited improvements in progression-free and overall survival. Precision oncology, encompassing molecular diagnostics and targeted therapies, is increasingly being integrated, but drug resistance and the limited options for HER2-negative patients highlight the urgent need for innovative therapies, including bispecific antibodies and novel immune checkpoint inhibitors, to improve clinical outcomes.
- **EPNEC:** For EP-NEC, combination therapy is the first-line SOC for most patients. Second-line treatment depends on biomarkers: patients with a high Antigen Kiel (Ki) 67 index (>55%) often receive combination regimens like CAPTEM or oxaliplatin-based therapies such as oxaliplatin and capecitabine (XELOX) as well as folinic acid, fluorouracil and oxaliplatin (FOLFOX), while those with a lower Ki-67 index (<55%) may benefit from temozolomide monotherapy. Patients with dMMR/MSI-H tumors, a smaller subgroup (5% to 10%), are treated with immune checkpoint inhibitors.

Source: Frost & Sullivan analysis

Appendix

- Gastric cancer treatment strategies vary based on the stage of the disease, with distinct approaches for early and advanced stages. For early-stage gastric cancer, ranging from stage I to stage III, surgery remains the SOC and is often complemented by adjuvant chemotherapy to reduce recurrence risk. Commonly used regimens include combinations of oxaliplatin with fluorouracil (5-FU) or capecitabine, as well as cisplatin-based therapies. In cases of non-metastatic, resectable gastric cancer, neoadjuvant therapy, which involves agents like docetaxel, cisplatin, and 5-FU, is employed to shrink tumors before surgery. However, for unresectable cases, simultaneous radiotherapy and chemotherapy are critical, typically using carboplatin, paclitaxel, or cisplatin-based regimens. For advanced metastatic gastric cancer, usually refers to stage IV, the focus shifts to systemic therapies aimed at prolonging survival and improving quality of life.
- **SCLC**: Over 90% of advanced SCLC patients receive the first-line treatment. After several decades, chemotherapy remains the standard first-line treatment for extensive-stage SCLC, with regimens such as etoposide plus carboplati, etoposide plus carboplatin (EC) or atezolizumab plus EC playing a central role. Although these patients initially respond well to chemotherapy, most eventually relapse due to drug resistance. In such cases, second-line or third-line therapies, including agents like topotecan and nivolumab, are utilized to manage disease progression. It is estimated that 70% to 80% of patients are eligible for first-line combination treatments, while 20% to 30% qualify for monotherapy or combination therapies in later treatment lines, reflecting a tailored approach to managing this challenging disease.
- **NSCLC**: In China, approximately 30% to 40% of patients are eligible for targeted therapies, while in the U.S., this proportion is around 15% to 20%, and patients without actionable driver mutations, systemic chemotherapy or immunotherapy is broadly applied.
- **BTC**: Around 80% of advanced BTC patients receive the first-line treatment.

Source: Frost & Sullivan analysis

Appendix

- In comparison, according to the publicly reported clinical data of Genmab's acasunlimab, in combination with Keytruda® for the treatment of metastatic NSCLC, 13.3% of the patients experienced Grade 3 or above liver-related adverse events. Such clinical data in comparison was generated from its respective clinical studies according to publicly available source, not from head-to-head studies with LBL-024. The observed differences in efficacy outcomes may be influenced by various factors, including but not limited to differences in patient baseline characteristics, disease status, prior treatment history, and study design parameters across these independent trials. Therefore, these cross-trial comparisons should be interpreted with caution.
- MM: In both China and the U.S., combination regimens, particularly those based on bortezomib, are widely used for 70% to 80% of patients, while monotherapy is typically reserved for 20% to 30% based on factors like transplantation eligibility and disease progression. However, relapsed or recurrent multiple myeloma highlights the need for more effective and less toxic options.
- ADC: Advances in ADC design and conjugation technologies have seen significant progress since the first FDA approval in 2000. This momentum is largely driven by the successful launch of innovative drugs like Enhertu (HER2-directed) in 2019, Padcev (Nectin-4-directed) in 2019, and Trodelvy (TROP2-directed) in 2020. With 12 FDA-approved ADCs now on the market, these therapies have evolved from being limited to late-line blood cancer treatments to a promising early-line option for a wider array of solid tumors and other medical conditions.
- The research and development of T-cell engagers has received widespread attention. Recently, a number of blockbuster license deals regarding T-cell engager have been made. EpimAb Biotherapeutics and Vignette Bio announced strategic collaboration to develop EMB-06, a BCMA×CD3 bispecific antibody in Sept 2024; EpimAb will receive total upfront considerations of $60 million in cash and equity of Vignette, and will be eligible to receive up to $575 million development, regulatory and commercial milestones, plus royalties on net sales. WuXi Bio signed $1.5bn TCE antibody pact with GSK; under the agreement, WuXi Biologics will receive $40 million upfront and up to $1.46 billion in milestones for the four TCE antibodies, plus royalties.

Source: Frost & Sullivan analysis

Appendix

NCT	Phase	Treatment	Patient Number	Indication	Treatment Line	ORR(%)	mPFS(m)	mOS(m)
NCT05170958	I/II	LBL-024	45	EP-NEC	≥2L	33.3%	2.8	15
NCT05170958	I/II	LBL-024	21	EP-NEC	2L	38.1%	4.1	Not reached
NCT04169672	II	Surufatinib + Toripalimab	21	NEC	2L	23.8%	4.1	10.9
NCT03167853	Ib	Toripalimab	40	NEN	≥2L	20.0%	2.5	7.8
NCT02820857	II	FOLFIRI	67	NEC	2L	18.3%	3.5	8.9
NCT03136055	II	Pembrolizumab	14	EP-NEC	≥2L	7.0%	1.8	7.8
NCT03591731	II	Nivolumab	83	NEC	≥2L	7.2%	1.8	7.2
		Nivolumab + Ipilimumab	87	NEC	≥2L	14.9%	1.9	5.8
NCT02955069	II	PDR001	21	GEP-NEC	≥2L	4.8%	1.8	6.8
NCT03095274	II	Durvalumab+Tremelimumab	18	GEP-NEC	2L	16.7%	2.4	5.9
NCT04400474	II	Cabozantinib+Atezolizumab	9	G3 EP-NEN	≥2L	0	2.7	5.4

Source: Frost & Sullivan analysis

Appendix

LBL-024, Cancer	2019		2023		2030E	
	Incidence, thousand	Market size, billion USD	Incidence, thousand	Market size, billion USD	Incidence, thousand	Market size, billion USD
EP-NEC	48.2	2.4	61.9	3.1	81.2	7.3
SCLC	341.9	2.6	382.8	4.1	461.3	9.1
NSCLC	1,937.6	50.2	2,169.4	78.3	2,614.3	165.1
BTC	356.3	0.9	405.7	1.9	505.0	7.7
ESCC	329.3	1.1	367.8	1.8	441.3	6.9
HCC	721.0	2.2	800.3	3.6	952.0	10.3
GC	893.7	14.0	995.5	18.2	1,191.8	33.2

LBL-007, Cancer	2019		2023		2030E	
	Incidence, thousand	Market size, billion USD	Incidence, thousand	Market size, billion USD	Incidence, thousand	Market size, billion USD
NPC	113.7	0.3	122.8	0.4	138.8	1.0
NSCLC	1,937.6	50.2	2,169.4	78.3	2,614.3	165.1
CRC	1,849.1	16.9	2,031.5	22.9	2,402.4	43.7
ESCC	329.3	1.1	367.8	1.8	441.3	6.9
HNSCC	801.1	3.3	876.6	5.1	1,017.5	8.7

Source: Frost & Sullivan analysis

Appendix

Differences between the conditional approval and full approval

	Conditional Approval	Full Approval
Basis for Approval	• Surrogate endpoints • Intermediate clinical endpoints • early - stage clinical trial data	• Completed and comprehensive clinical trial data, covering various aspects such as long - term safety and efficacy.
Research Commitment	• Complete relevant studies as required within the specified time limit (in principle, not exceeding 4 years).	• Comprehensive research has been completed before approval. No need to undertake large - scale confirmatory research tasks
Continuous Monitoring	• Submit a written report on the progress of post-marketing studies to the CDE every 12 months.	• Post - approval continuous monitoring mainly focuses on routine adverse reaction reports and product quality stability.
Validity Period	• The validity period of the drug registration certificate is adjusted to 5 years.	• Enterprises can plan pharmaceutical activities in the long term without the need for frequent reregistration.

Source: CDE, Frost & Sullivan analysis

Appendix

Modality	Mechanism	Status
CAR-T Cell Therapy	Genetically engineered T cells express chimeric antigen receptors (CARs) to specifically recognize tumor cell surface antigens，activating T cell-mediated tumor killing and secreting cytokines to enhance immune responses.	Clinical trials ongoing for solid tumors
Antibody-Drug Conjugates (BsADCs)	Bispecific antibody-drug conjugates (BsADCs) are drugs formed by conjugating small-molecule cytotoxic payloads to bispecific antibodies via a linker. They can effectively target and deliver cytotoxic agents to cancerous cell regions, achieving precise therapeutic effects.	Clinical trials ongoing for solid tumors
RNA-Targeted Small Molecules	Directing splicing — by acting as molecular glues with cellular proteins, inhibition of translation of undruggable proteins and deactivation of functional structures in noncoding RNAs.	Clinical trials ongoing for solid tumors
Gene therapy	Use CRISPR technology to edit genes in immune cells, knocking out inhibitory receptors or inserting genes to enhance anti-tumor functions, improving infiltration and killing of solid tumors.	Early clinical trials
Cancer Vaccines	Deliver tumor antigens to activate the immune system, inducing specific T cell responses against tumor-associated antigens (TAAs) or neoantigens.	Clinical trials
PROTACs	Proteolysis Targeting Chimeras (PROTACs) utilize the cell's natural protein degradation machinery, the ubiquitin-proteasome system (UPS), to enable targeted degradation of proteins of interest (POI).	Clinical trials ongoing for solid tumors

Source: Literature Review, Frost & Sullivan analysis

Competitive Landscape of Immune Checkpoint Inhibitors by FDA

Target	Drug Name	Indications	FDA Approval Date
LAG3	Nivolumab + Relatlimab （OPDUALAG）	Unresectable or Metastatic Melanoma	2022-03-18
CTLA-4	YERVOY (Ipilimumab)	Previously treated unresectable/metastatic melanoma; RCC, CRC, HCC, NSCLC, MPM, EC	2011-03
	Imjudo (Tremelimumab)	Adult patients with unresectable hepatocellular carcinoma (HCC); NSCLC	2022-10

As of Mya 9th 2025

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Competitive Landscape of Immune Checkpoint Inhibitors by FDA

Target	Drug Name	Indications	FDA Approval Date
PD-1/PD-L1	JEMPERLI (Dostarlimab)	dMMR recurrent/advanced endometrial cancer; dMMR solid tumors	2021-04
	OPDUALAG (Nivolumab + Relatlimab)	Unresectable/metastatic melanoma (>12 years)	2022-03
	Zynyz (Retifanlimab)	Adult patients with metastatic/recurrent locally advanced Merkel cell carcinoma (MCC)	2023-03
	Toripalimab	First-line treatment for adult metastatic/recurrent locally advanced nasopharyngeal carcinoma; recurrent/unresectable/metastatic nasopharyngeal carcinoma progressed on platinum-based chemo	2023-10
	Tislelizumab	Adult patients with unresectable/metastatic esophageal squamous cell carcinoma (ESCC) who received prior systemic chemo without PD-(L)1 inhibitors	2024-03
	UNLOXCYT	CSCC	2024-12-13
	PENPULIMAB-KCQX	NPC	2025-04-23

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

As of May 9th 2025