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**Genscript Biotech Corporation**

**金斯瑞生物科技股份有限公司\***

*(Incorporated in the Cayman Islands with limited liability)*

**(Stock code: 1548)**

**CLARIFICATION ANNOUNCEMENT  
AND  
RESUMPTION OF TRADING**

This announcement is made by Genscript Biotech Corporation (the “**Company**”, together with its subsidiaries, the “**Group**”) with respect to a report recently issued by Flaming Research (“**Flaming**”) (the “**Report**”) which contains allegations against the Company, and is published by the Company pursuant to Rule 13.09 of the Rules Governing the Listing of Securities (the “**Listing Rules**”) on The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong) (the “**SFO**”) to refute and/or clarify the allegations made in the Report.

The Company denies all of the allegations against the Company in the Report. As explained in detail below, the Report comprises statements which are misleading, biased, selective, inaccurate and incomplete as well as groundless allegations and irresponsible speculations.

The Company has no information on the identity of Flaming. The management of the Company has no record of being contacted by Flaming before and after the Report is published. The Company believes that Flaming’s ultimate aims are to drive down the price of the Shares and undermine the Company’s reputation. The Company is consulting its legal advisers and will consider taking legal actions against Flaming.

## INFORMATION ABOUT THE GROUP

Genscript Biotech Corporation was founded in New Jersey, US in 2002. In our early days, we mainly provided gene synthesis services to our customers. In 2004, in order to suit the fast growth of our business, the company established a research center in Nanjing. At the end of 2015, Genscript was successfully listed in Hong Kong. The proprietary gene synthesis technology platform is the base for our business—a steady support for Genscript’s future development. So far, Genscript has kept its leading position in global gene synthesis market. Building on the strong gene synthesis tech platform, we have developed a comprehensive one-stop life science CRO service platform, an antibody drug development platform, an industrial expression biotech platform and an innovation CAR T-cell therapy platform.

As a leading biotech company, we believe R&D and talents are the source of sustainable business growth. In recent years, we have kept devoting around 10% of our annual revenue to the R&D in our traditional business. During the first half of 2018, Genscript invested 27% of its revenue on R&D. With such intense investment on R&D, we have built a rich patent reserves. Currently, the Group owns 54 patents, and 142 patent applications are under examination. Regarding the talents, as of 30 June 2018, 631 of our staff have masters and above degrees, including 140 Ph.Ds. Meanwhile, Legend’s R&D team has doubled in size over the same period last year.

The Company has been assisting its customers in preparing antibodies since 2005. In 2008, the Company commenced the development of antibody design and anti-antibody engineering, in vitro testing and in vivo testing, and has successfully assisted internationally renowned companies in developing antibodies for drugs. Antibody design and development are the core of CAR-T development. The Company, through the development of antibody drugs, has accumulated technology and laid a solid foundation for the development of CAR-T. The Company’s current operations and financial position are stable. In order to avoid the Report from misleading investors, the Company hereby clarifies the content of the Report as follows.

## CLARIFICATIONS

### **Allegation 1:** About the Company’s Clinical Data Disclosure

#### ***The Company’s response:***

All the clinical data disclosed by the Company are true and traceable. The Company has never committed fraud or selectively disclosed its clinical trial data. Instead, as the Company is deeply rooted in its belief in science and authenticity, it made timely disclosure whenever appropriate as the clinical trial progresses. Before IND (investigational new drug) application, all clinical trials conducted by Nanjing Legend Biotechnology Co., Ltd.\* 南京傳奇生物科技有限公司 (“**Legend**”), a wholly-owned subsidiary of the Company, were “Researcher Initiated Clinical Trials”. In 2016, the Company partnered with the Second Affiliated Hospital of Xi’an Jiaotong University\* 西安交通大學第二附屬醫院, a “Triple A” hospital eligible for clinical trials.

The 2017 ASCO (American Society of Clinical Oncology) meeting was held in June, with the deadline for submitting papers set in February 2017. Therefore, the data the Company released at the ASCO meeting in June 2017 regarding the clinical trials at the Second Affiliated Hospital of Xi'an Jiaotong University were dated no later than February 2017. Legend's cooperation with Shanghai Ruijin Hospital\* 上海瑞金醫院, Shanghai Changzheng Hospital\* 上海長征醫院 and Jiangsu Province People's Hospital\* 江蘇省人民醫院 were all established after the paper submission deadline (February 2017) of the ASCO meeting, so it is impossible to disclose the data generated by the three hospitals at the meeting in June 2017.

On 3 December 2017, Shanghai Ruijin Hospital\* 上海瑞金醫院, Shanghai Changzheng Hospital\* 上海長征醫院 and Jiangsu Province People's Hospital\* 江蘇省人民醫院 made a joint publication of 11 cases of relapsed/refractory multiple myeloma at the ASH (American Society of Hematology) meeting. Out of the 11 cases, 8 patients achieved sCR (stringent complete remission) (73%), 2 achieved VGPR (very good partial response), and 1 achieved PR (partial response), yielding 100% of ORR (overall response rate), showing outstanding efficacy.

Legend has completed 74 cases in China with consistent effectiveness and safety supported by historical data.

All data collected by Legend have been submitted to the China Food and Drug Administration (the "CFDA") and the Food and Drug Administration ("FDA") of the United States. Legend has obtained CDA approval to conduct confirmatory clinical trials through multiple centers in China in March 2018. Meanwhile, Legend has been approved to carry out Phase 1b and Phase 2 clinical trials in the United States in May 2018, where clinical recruitment has gone smoothly and the patients have already started the treatment.

**Allegation 2:** About Legend's CAR-T Design Innovation and its Preparation Process

***The Company's response:***

Flaming claims that Legend uses "the CD28 costimulatory domain, a failure demonstrated by JUNO's JCAR015 that most CAR-T companies should avoid". This is a blatant slander, because Legend has never used CD28 costimulatory domain in its CAR design. In fact, it uses 4-1BB costimulatory domain in the design, thus free from any consequential risks speculated in the Report.

Legend's bispecific antibody is developed based on its proprietary technology platform, one of the vital reasons for its effectiveness. Bispecific antibody can bind with antigens more tightly, thus preventing antigen escape of the cancer cells.

Legend has mastered the process to prepare and develop bispecific CAR-T products featured by steady consistency. And it has successfully prepared 74 batches of CAR-T products for its patients in China. Drawing on its experience in this field. Legend has already provided its products to US patients.

Legend's CAR-T product received CFDA's approval for confirmatory clinical trials in March 2018 and FDA's approval for clinical trials in May 2018. The Company believes that the commercialization of the product is steadily under way.

### **Allegation 3: About the Company's Technology Development and its Background**

#### ***The Company's response:***

Genscript Biotech Corporation is a global leader in custom biologic reagent services. After years of fast growth, the Company has covered a wide range of businesses, including but not limited to precision immunotherapy, custom biologics development (CDMO), biologic reagent products and instruments, synthetic biology and industrial microorganism application. Ever since 2008, the Company has been providing bispecific nanobody-based contract research organization (CRO) services to its customers through its proprietary nanobody drug platform. So far, it has accumulated years of technological experience in antibody design and development.

Dr. Frank Fan, CSO of Legend, was a director of the Company's antibody and protein engineering department at GenScript Corporation, the head of nanobody development platform. He obtained his medical degree at the Medical School of Xi'an Jiaotong University and worked as a surgical resident at the Kidney Transplantation Centre at the First Affiliated Hospital of Xi'an Jiaotong University. After that, he received his PhD in the field of transplant immunology at the Hiroshima University and pursued his postdoctoral research in transplantation immunology at the Hospital for Sick Children, University of Toronto, Canada. In 2014, Dr. Fan joined the Company. Dr. Fan has devoted years to the research in applied immunology and gene therapy, and has made significant breakthroughs in field of organ transplant.

In fact, CAR-T technology is an innovation of the academic community by combining immunology gene therapy with clinical medicine. In 2004, Dr. Fan made an important breakthrough in children heart transplant with different blood type and published a paper as the first author in Nature Medicine, a top science journal. The paper attracted the world's attention and was reported by several news outlets. Dr. Fan's discovery changed clinical guidance on tissue typing in organ transplant and overhauled the disease clinical standard, thus improving children's odds at transplant survival. Over the years, Dr. Fan has published over 40 academic papers in gene therapy and human immunotherapy, and was listed as the first author in 15 of them.

The Company's scientist team led by Dr. Fan has shown extraordinary devotion to CAR-T research and made significant breakthroughs in this area. Currently, there are 2 CAR-T R&D teams in China, with a total of over 140 staff. Also, two more teams, one in the US and the other in Europe are working together with the Chinese teams to push forward our pipeline development and commercialization.

**Allegation 4:** About the Company’s IP Protection Mechanism and Patent Granting Prospect

***The Company’s response***

Legend has developed a complete patent portfolio for its proprietary technology, which paves a bright path for its IP granting.

Currently, Legend has obtained three patents and filed 70 patent applications (including 27 PCT applications, seven Chinese patent applications and 37 overseas patent applications), among which, 48 applications are directly related to cell therapy. One core patent (PCT/CN2016/094408) of LCARB38M has entered into 29 countries/regions. Another one core patent PCT/CN2017/096938 will enter into national phase soon, and is expected to enter into the same 29 countries/regions. The two PCT applications have shown promise of granting.

“Conflicted Patents” used in the Report (Table 3. Overview of Legend Biotech’s CAR-T Related Patent Applications) was actually a coined word, re-invented from “Documents Considered to be Relevant” in International Search Report on the World Intellectual Property Organization. The term is a blatant disguised replacement of concept with misleading purpose. The documents listed in International Search Report are for reference only with no legal binding force (Article 33 of “Patent Cooperation Treaty”). Therefore, that patent applications would be rejected based merely on International Search Report’s referential is ridiculous and a groundless conclusion. According to public information, and taking Merck’s PD-1 antibody (hereinafter Drug K) and Bristol-Myers Squibb’s PD-1 (Drug O) as an example, Drug O’s Compound Patent WO2006121168 was listed as the so-called “Conflicted Patent” of Drug K’s Compound Patent WO2008156712, but Drug K has finally gained patents in Australia, China, Canada, the Europe, Japan, South Korea, the United States and other countries, a proof that “Documents Considered to be relevant” in International Search Report has no binding force upon patent examination in specific countries.

**Allegation 5:** About the Disclosure of the Death of the Patient

***The Company’s response:***

On September 16 2017, after the death incident, the Company immediately notified all researchers in the form of a researcher’s letter and disclosed the incident to the public on 19 September 2017, without any concealment as mentioned in the Report. All medical documents regarding the patient has been reported to CDE and FDA, and have been reviewed and assessed by professionals. Legend subsequently received approval for clinical trial by CDE in March 2018 and approval for clinical trial by FDA in May 2018.

**Allegation 6:** About the Change in the Shareholdings of the Management and the Equity Investment by Legend

***The Company's response:***

The founders are also one of our vital shareholders. The shares sold by Genscript Corporation accounted only for 1.15% of the total, and the company still holds 48.4% of the total shares.

Decrease in shareholdings by Ms. Wang Ye was due to her exercise of option which would fall due soon and as a taxpayer in the US. Ms. Wang Ye has not reduced the shareholdings of listed companies held by Genscript Corporation.

Legend is an innovative biotech company, and scientists and management teams are the key assets of the company. So, we include our scientists and management teams in share investment plans as disclosed in the Company's announcement on 20 October 2017 and option schemes, a common practice of innovative high-tech company and an important way to maintain our innovative force and realize our corporate value. The decision to launch share investment plans and option schemes was made by the Board after careful deliberation. For more information, please refer to the announcements on 28 June 2017, 17 July 2017 and 20 October 2017.

**Allegation 7:** About Market potentials of CAR-T's products.

***The Company's response:***

Emily Whitehead, an American lady, is the first to successfully receive CAR-T precision cell therapy and has been considered as cancer free for six years. In the field of medicine, five years of disease free survival is defined as cured. This is one of the reasons why CAR-T technology has attracted much attention in the world.

In the United States, there are currently approximately 25,000 new cases of multiple myeloma each year, and the current number of patients is approximately 125,000, according to the market research report on multiple myeloma. If CAR-T is priced at \$350,000 (according to public information, Novatis' CAR-T product Kymriah's CAR-T product is priced at \$475,000 and Kite Pharma's CAR-T product is priced at \$373,000), then the potential market in the United States is approximately \$8.7 billion per year. This market forecast does not include other countries and regions.

In addition to developing CAR-T cell therapy for multiple myeloma, Legend is also developing a variety of cancers including lymphoma, gastric cancer, and brain keratinoma. The Company believes that the market prospects of CAR-T is promising.

## **RESUMPTION OF TRADING**

At the request of the Company, trading in the shares of the Company on the Stock Exchange was halted with effect from 11:32 a.m. on Thursday, 27 September 2018 pending release of this announcement. The Company has applied to the Stock Exchange for resumption of trading in its shares on the Stock Exchange with effect from 9:00 a.m. on Friday, 28 September 2018.

**Shareholders and potential investors of the Company are advised to exercise caution when dealing in the securities of the Company.**

By Order of the Board  
**Genscript Biotech Corporation**  
**Dr. Zhang Fangliang**  
*Chairman and Chief Executive Officer*

Hong Kong, 28 September 2018

*As at the date of this announcement, our executive Directors are Dr. ZHANG Fangliang, Ms. WANG Ye, and Mr. MENG Jiange; our non-executive Directors are Dr. WANG Luquan and Mr. PAN Yuexin; and our independent non-executive Directors are Mr. GUO Hongxin, Mr. DAI Zumian, and Ms. ZHANG Min.*

\* *For identification purposes only*