

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



丽珠医药
LIVZON

麗珠醫藥集團股份有限公司

LIVZON PHARMACEUTICAL GROUP INC.*

(a joint stock company incorporated in the People's Republic of China with limited liability)

(Stock code: 1513)

Overseas Regulatory Announcement

This announcement is made pursuant to Rule 13.10B of the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited.

Set out below is the “ANNOUNCEMENT ON THE APPROVAL OF APPLICATION FOR CLINICAL TRIAL ON A NEW DRUG” of Livzon Pharmaceutical Group Inc.* published on the website of the Shenzhen Stock Exchange, which is set out herein for information purpose only.

The abovementioned announcement is prepared in Chinese, if there is any discrepancy between the Chinese version and the English version, the Chinese version shall prevail.

By order of the Board
Livzon Pharmaceutical Group Inc. *
麗珠醫藥集團股份有限公司
Yang Liang
Company Secretary

Zhuhai, China
19 February 2020

As at the date of this announcement, the Executive Directors of the Company are Mr. Tang Yanggang (President) and Mr. Xu Guoxiang (Vice Chairman and Vice President); the Non-Executive Directors of the Company are Mr. Zhu Baoguo (Chairman), Mr. Tao Desheng (Vice Chairman) and Mr. Qiu Qingfeng; and the Independent Non-Executive Directors of the Company are Mr. Xu Yanjun, Mr. Zheng Zhihua, Mr. Xie Yun, Mr. Tian Qiusheng and Mr. Wong Kam Wa.

* For identification purpose only

LIVZON PHARMACEUTICAL GROUP INC. ANNOUNCEMENT ON THE APPROVAL OF APPLICATION FOR CLINICAL TRIAL ON A NEW DRUG

The Company and all members of the Board of Directors guarantee all contents of the disclosed information are true, accurate and complete, and no false representation, misleading statement or material omission is made.

Recently, the application for Investigational New Drug (“IND”) on Recombinant anti-human IL-17A/F Humanized Monoclonal Antibody Injection jointly submitted by Livzon MabPharm Inc.* (珠海市麗珠單抗生物技術有限公司) (“Livzon MabPharm”), a controlling subsidiary of Livzon Pharmaceutical Group Inc.* (麗珠醫藥集團股份有限公司) (the “Company”) and Beijing Kanova BioPharm Technology Co., Ltd.* (北京鑫康合生物醫藥科技有限公司) (“Kanova BioPharm”) was approved by the China National Medical Products Administration (“NMPA”). Details are as follows:

I. Key description of the IND application

Product name: Recombinant anti-human IL-17A/F Humanized Monoclonal Antibody Injection

Chinese name: 重組抗人 IL-17A/F 人源化單克隆抗體注射液

Dosage form: solution for injection

Strength: 100 mg/1 mL

Item for application: Investigational New Drug

Category of registration: Class 1 of therapeutic biological products

Applicants: Livzon MabPharm Inc.* (珠海市麗珠單抗生物技術有限公司) and Beijing Kanova BioPharm Technology Co., Ltd.* (北京鑫康合生物醫藥科技有限公司)

Approval conclusion: According to the Drug Administration Law of the People's Republic of China (《中華人民共和國藥品管理法》) and relevant regulations, upon review, Recombinant anti-human IL-17A/F Humanized Monoclonal Antibody Injection accepted on 11 November 2019 met the relevant requirements for IND, the initiation of clinical trial was approved. Indications: Moderate to severe plaque psoriasis.

II. Research and development of the drug and relevant information

The Company took 4 years to develop the “Recombinant anti-human IL-17A/F Humanized Monoclonal Antibody Injection” and the IND application was approved on 19 February 2020 with the application number CXSL1900130.

Recombinant anti-human IL-17A/F Humanized Monoclonal Antibody Injection can target homodimer IL-17A-A and IL-17F-F and heterodimer IL-17A-F in the same time. In the body, IL-17A and IL-17F exist in the form of homodimer IL-17A-A and IL-17F-F and heterodimer IL-17A-F. They are mainly secreted by T helper cells Th17 sub-group, and also by other T cells, neutrophil, and mast cells. These dimers act on the receptors IL-17RA and IL-17RC, which can promote the expression of other pro-

inflammatory cytokines (such as IL-6, TNF α , IL-1 β , IL-20 family cytokines, GM-CSF) and effector proteins, and further cause activation of neutrophils and macrophages, as well as epithelial cells and fibroblasts, thus they play an important role in the pathophysiology of many autoimmune diseases.

As of the date of the announcement, the Company has accumulated research input of RMB39.2376 million in “Recombinant anti-human IL-17A/F Humanized Monoclonal Antibody Injection”.

III. Market condition of similar drugs

As to IL-17A target: currently, there are two imported products which were granted launch approval in Mailand, China in 2019, and 5 other domestic enterprises which were granted clinical trials, all of which are in the early clinical development stage.

As to IL-17A/F target: currently, this target is neither launched around the world, nor applied for clinical trials by other domestic companies in China.

IV. Approval procedures that are required for launch approval of the product

Though the IND application of the products is approved, the product cannot be launched into market until it undertakes clinical trials and GMP certification and obtains the approval from NMPA

V. Risk Warning

Due to the special nature of research and development of products, the period from IND approval to launch is long and involves many steps, which are susceptible to many unpredictable factors. There is still uncertainty as to whether it can be granted approval for clinical trials. The Company will timely perform its obligations of information disclosure based on subsequent progress. Investors are advised to be aware of the risks on investment.

Notice is hereby given.

Board of Directors of Livzon Pharmaceutical Group Inc. *

20 February 2020

** For identification purpose only*