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**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 DRUG CLINICAL TRIAL APPROVAL FOR SEMAGLUTIDE INJECTION” 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

05 February 2024

*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), Mr. Qiu Qingfeng and Mr. Yu Xiong; and the Independent Non-Executive Directors of the Company are Mr. Bai Hua, Mr. Tian Qiusheng, Mr. Wong Kam Wa, Mr. Luo Huiyuan and Ms. Cui Lijie.*

*\* For identification purpose only*

## **LIVZON PHARMACEUTICAL GROUP INC. ANNOUNCEMENT ON DRUG CLINICAL TRIAL APPROVAL FOR SEMAGLUTIDE INJECTION**

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.

Livzon Group Xinbeijiang Pharmaceutical Manufacturing Inc.\* (麗珠集團新北江製藥股份有限公司) (“Xinbeijiang Pharma”), the controlling subsidiary of Livzon Pharmaceutical Group Inc.\* (麗珠醫藥集團股份有限公司) (the “Company”), has recently received the Notice of Drug Clinical Trial Approval (Notice No: 2024LP00324, 2024LP00325) issued by China National Medical Products Administration, approving to conduct the clinical trials of Semaglutide Injection for weight management indications in accordance with the technical requirements of biosimilars. The relevant details are now disclosed as follows:

### **I. MAIN CONTENTS OF THE NOTICE OF DRUG CLINICAL TRIAL APPROVAL**

Drug name: 司美格魯肽注射液

English/Latin name: Semaglutide Injection

Dosage form: injection (solution for injection)

Application: clinical trial application

Registration classification: a therapeutic biological product in Category 3.3

Applicant: Livzon Group Xinbeijiang Pharmaceutical Manufacturing Inc.\*

Review conclusion: According to the Pharmaceutical Administration Law of the People’s Republic of China (《中華人民共和國藥品管理法》) and the relevant regulations, upon review, the clinical trial application for Semaglutide Injection accepted on 30 November 2023 satisfied the relevant requirements for drug registration, and this product was approved to conduct the clinical trials for weight management indications in accordance with the technical requirements of biosimilars.

### **II. RESEARCH AND DEVELOPMENT OF DRUG AND RELATED CONDITIONS**

Semaglutide Injection (the “Product”) is a biosimilar independently developed by the Company. The indication approved for clinical trials this time is chronic weight management in adult patients with an initial body mass index (BMI) value of 30 kg/m<sup>2</sup> or above (obesity) or 27 kg/m<sup>2</sup> or above (overweight) and with at least one weight-related comorbidity (such as hypertension, dyslipidemia, fatty liver, obstructive sleep apnea syndrome). The enrollment of phase III clinical trial of the Product for type II diabetes indication has been completed. For details of the Product,

please refer to the Indicative Announcement on Acceptance of Clinical Trial Application on A Drug (Announcement No.: 2021-083) of the Company dated on 15 September 2021. For the research and development progress of the Product, please refer to the announcements published by the Company in the statutory information disclosure newspapers and websites.

As at the date of this announcement, the cumulative direct investment in research and development expenses for Semaglutide Injection is approximately RMB126.9598 million, of which approximately RMB71.9215 million has been capitalized.

### **III. MARKET CONDITIONS OF THE DRUG**

According to the website of CDE (Center for Drug Evaluation), as at the date of this announcement, for the weight management indication of Semaglutide Injection, there are no imported or domestic products on the market, and a total of three companies have been approved for clinical trials (including Xinbeijiang Pharma).

### **IV. RISK WARNING**

Due to the special nature of the research and development of drug, and the long cycle from clinical trials to manufacturing and marketing involving many stages which are susceptible to many unpredictable factors, there are many uncertainties in the progress and results of clinical trials and the competition in the future product market. The Company will fulfil its information disclosure obligations in a timely manner according to the progress of research and development, and investors are kindly advised to pay attention to investment risks.

Notice is hereby given.

**Board of Directors of Livzon Pharmaceutical Group Inc. \***

**06 February 2024**

*\* For identification purpose only*