

*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 “INDICATIVE ANNOUNCEMENT ON ACCEPTANCE OF REGISTRATION AND MARKETING AUTHORIZATION APPLICATION OF 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  
12 June 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.  
INDICATIVE ANNOUNCEMENT ON ACCEPTANCE OF  
REGISTRATION AND MARKETING AUTHORIZATION  
APPLICATION OF 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 Pharmaceutical”), a 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 Acceptance (Acceptance No.: CXSS240005) approved and issued by National Medical Products Administration (“NMPA”). Xinbeijiang Pharmaceutical’s application for the domestically manufactured drug registration of Semaglutide Injection was accepted by NMPA. The relevant details are now disclosed as follows:

**I. THE MAIN CONTENTS OF THE NOTICE OF ACCEPTANCE**

Drug name: 司美格魯肽注射液

English/Latin name: Semaglutide Injection

Dosage form: Injection (solution for injection)

Specification: 1.34mg/ml, 1.5ml (pre-filled pen), 1.34mg/ml, 3ml (pre-filled pen), 1.34mg/ml, 3ml (refill)

Application: registration and marketing authorization for the domestically manufactured drug

Registration classification: a therapeutic biological product in Category 3.3

Applicant: Livzon Group Xinbeijiang Pharmaceutical Manufacturing Inc.\* (麗珠集團新北江製藥股份有限公司)

Review conclusion: It has been determined after review that the application was accepted in accordance with the provision of Article 32 of the Administrative License Law of the People’s Republic of China (《中華人民共和國行政許可法》).

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

Semaglutide Injection (the “Product”) is a biosimilar independently developed by the Company. The indications for this registration application are: for the blood sugar control of adult patients with type 2 diabetes who has received, on the basis of diet control and exercise, the treatment of metformin and/or sulfonylureas but failed to control their blood sugar, and for reducing the risk of major adverse cardiovascular events (such as cardiovascular death, non-fatal myocardial

infarction, or non-fatal stroke) in adult patients with type 2 diabetes as well as cardiovascular diseases.

The clinical trials for the weight management indication of the Product were approved in February 2024. For details of the Product, please refer to the Announcement on Drug Clinical Trial Approval for Semaglutide Injection (Announcement No.: 2024-010) of the Company dated on 6 February 2024 and 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 disclosure date of this announcement, the accumulated direct investment in research and development of Semaglutide Injection is approximately RMB141.3956 million, of which RMB80.4227 million is capitalized.

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

According to NMPA and the database from the website of CDE (Center for Drug Evaluation), as at the disclosure date of this announcement, one original product of Semaglutide Injection has launched for market and two companies have applied for registration and marketing authorization (including Xinbeijiang Pharmaceutical).

According to the sampling statistical estimates from IQVIA, the domestic sales to end customers of diabetes medications in 2023 amounted to RMB34,580 million, among which the domestic sales to end customers of GLP-1 agonist drugs amounted to RMB6,058 million.

### **IV. RISK WARNING**

According to the requirements of national laws and regulations relating to drug registration, Semaglutide Injection will be transferred to CDE for review and approval after the application for registration has been accepted by NMPA, with uncertainties in the completion time and the approval result. The Company will fulfill its information disclosure obligations in a timely manner according to the progress of research and development, and investors are kindly advised to make prudent decisions and pay attention to investment risks.

Notice is hereby given.

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

**13 June 2024**

*\* For identification purpose only*