

*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 OBTAINING THE U.S. FDA APPROVAL FOR THE COMPANY’S DRUG CETRORELIX ACETATE FOR 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  
26 April 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 OBTAINING THE U.S. FDA APPROVAL FOR THE COMPANY'S DRUG CETRORELIX ACETATE FOR 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.

Recently, Livzon Group Livzon Pharmaceutical Factory\* (麗珠集團麗珠製藥廠), a wholly-owned subsidiary of Livzon Pharmaceutical Group Inc.\* (麗珠醫藥集團股份有限公司) (hereinafter referred to as "the Company"), received the approval notice for the ADNA (ANDA number: 214540) issued by the U.S. Food and Drug Administration (hereinafter referred to as "U.S. FDA"), approving the market launch of Cetorelix Acetate for Injection developed by the Company in the United States. The relevant information is announced as follows:

### **I. GENERAL INFORMATION OF THE DRUG**

Drug name: Cetorelix Acetate for Injection (注射用醋酸西曲瑞克)

English name/Latin name: Cetorelix Acetate for Injection

Indications: Inhibition of premature ovulation in patients undergoing controlled ovarian stimulation

Dosage Form: Injection

Specification: 0.25mg/vial

ANDA No.: 214540

Validity: 24 months

Applicant: Livzon Group Livzon Pharmaceutical Factory\*

Manufacturer: Nanjing King-friend Biochemical Pharmaceutical Co., Ltd. (南京健友生化製藥股份有限公司)

### **II. OTHER RELEVANT INFORMATION OF THE DRUG**

Cetorelix Acetate for Injection is a third-generation gonadotropin-releasing hormone antagonist (GnRH-ant). Cetorelix Acetate for Injection has the advantages of rapid onset and low incidence of OHSS and adverse events. The Company's Cetorelix Acetate for Injection was approved for market launch in China on 31 December, 2021, and registration applications have been submitted in several overseas countries.

As at the disclosure date of this announcement, the accumulated direct research and development costs for Cetrotorelix Acetate for Injection amounted to approximately RMB22.9048 million.

### **III. MARKET CONDITION OF SIMILAR DRUGS**

As at the disclosure date of this announcement, Cetrotorelix Acetate for Injection from a total of four companies, including the original research company, (including Livzon Group Livzon Pharmaceutical Factory\*) have been approved for market launch in the U.S., and Cetrotorelix Acetate for Injection from a total of seven companies (including Livzon Group Livzon Pharmaceutical Factory\*) have been approved for market launch in China.

Upon enquiry, the global sales amount of Cetrotorelix Acetate for Injection in 2022 was approximately US\$216.00 million, of which approximately US\$105.00 million was from the U.S. market. Pursuant to the data from IQVIA sampling statistics assessment, the domestic terminal sales amount of Cetrotorelix Acetate for Injection in 2023 was approximately RMB241.6436 million.

### **IV. THE IMPACT ON THE COMPANY AND THE RISK WARNING**

The Cetrotorelix Acetate for Injection obtained the approval from the U.S. FDA, meaning the Company was qualified to sell the product as a drug in the U.S. market, which positively impacts the company's expansion into overseas markets and accumulates valuable experience. As the drug export business is vulnerable to changes in market demand, policy changes, exchange rate fluctuations, market competition and other factors, the sales scale and subsequent expansion progress of the product in the U.S. market are uncertain. Therefore, the investors are advised to invest rationally and pay careful attention to investment risks.

Notice is hereby given.

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

**27 April 2024**

*\* For identification purpose only*