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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 THE APPROVAL FOR CLINICAL TRIAL OF ALARELIN ACETATE MICROSPHERES 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

29 December 2021

*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 THE APPROVAL FOR CLINICAL TRIAL OF ALARELIN ACETATE MICROSPHERES 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.

On 28 December 2021, Shanghai Livzon Pharmaceutical Manufacturing Co., Ltd.\* (上海麗珠製藥有限公司) (“Shanghai Livzon”), a controlling subsidiary of Livzon Pharmaceutical Group Inc.\* (麗珠醫藥集團股份有限公司) (the “Company”) was granted the “Approval Notice for Clinical Trial on Drug” which was approved and issued by the China National Medical Products Administration to approve the commencement of the clinical trial of Alarelin Acetate Microspheres for Injection (注射用醋酸丙氨瑞林微球). The relevant details are now disclosed as follows:

### **I. THE MAJOR CONTENTS OF THE APPROVAL NOTICE FOR CLINICAL TRIAL ON DRUG**

Chinese Name of the Drug: 注射用醋酸丙氨瑞林微球

English/Latin Name: Alarelin Acetate Microspheres for Injection

Dosage Form: Injection

Application: Application for clinical trial

Registration classification: Chemical drug in Category 2.2; 2.4

Applicant: Shanghai Livzon Pharmaceutical Manufacturing Co., Ltd.\*

Review conclusion: It has been determined after review that Alarelin Acetate Microspheres for Injection accepted on 14 October 2021 meets the relevant requirements for drug registration and is approved to proceed with clinical trials based on the improved formula in accordance with the Pharmaceutical Administration Law of the People’s Republic of China and relevant regulations.

### **II. RESEARCH AND DEVELOPMENT OF THE DRUG AND RELEVANT PARTICULARS**

Alarelin Acetate Microspheres for Injection (the “Drug”) underwent four years of research and development (“R&D”) and the indication for this clinical trial application is prostate cancer. The Drug is a monthly subcutaneous formulation of gonadotropin-releasing hormone agonist, which could help reducing the frequency and stress of medication for patients. Alarelin acetate, the active ingredient, to which Shanghai Livzon has the exclusive approval, is a Class 1 original chemical drug in China and possesses a clear mechanism of action and treatment mechanism. Through dosage form optimization, Shanghai Livzon plans to develop it into a long-acting sustained-release microspheres (New Drugs in Category 2.2, which refer to drugs that contain known active ingredients with new dosage form, new

formulation process and new route of administration, and have clinical advantages) while undergoing R&D of new indications for the Drug (New Drugs in Category 2.4). In addition to the indication for prostate cancer, the Drug can also apply for the treatment of endometriosis, uterine fibroids, breast cancer, precocious puberty, assisted reproduction and other indications, thus further diversifying our R&D pipelines in relevant treatment fields.

As at the date of this announcement, the accumulated direct investment expenses in R&D of Alarelin Acetate Microspheres for Injection amounted to approximately RMB17.8185 million.

### **III. MARKET CONDITIONS OF DRUGS**

As at the date of this announcement, no other domestic or foreign manufacturers have obtained production approvals for Alarelin Acetate Microspheres for Injection. Currently, the relin-products for anti-tumor purposes used in the domestic market include Leuprorelin Acetate Microspheres for Injection (注射用醋酸亮丙瑞林微球), Goserelin Acetate Sustained-release Implant (醋酸戈舍瑞林缓释植入剂) and Triptorelin Acetate for Injection (注射用醋酸曲普瑞林). According to the sampling statistical estimates of IQVIA, the terminal sales of relin-medicines in the domestic market was approximately RMB7.449 billion in 2020, of which the sales of Leuprorelin Acetate Microspheres for Injection, Goserelin Acetate Sustained-release Implant and Triptorelin Acetate for Injection amounted to approximately RMB3.227 billion, RMB3.050 billion and RMB1.167 billion, respectively.

The Drug has demonstrated sound therapeutic effects in pre-clinical studies, but it will be launched to the market only after having completed the approval procedures including clinical studies and application for production approval. At present, there are products of the same category available in the domestic market, which have a stable market share. There are uncertainties regarding the Drug in terms of competition landscape and sales upon its launch.

### **IV. APPROVAL PROCEDURES SUBJECT TO FULFILMENT FOR MARKETING**

After obtaining the Approval Notice for Clinical Trial on Drug, Shanghai Livzon is required to conduct clinical studies in accordance with the contents of the approval, which is initially expected to take 2-3 years to complete the clinical studies, after which an application for manufacturing and marketing shall be submitted and the approval of such application shall be obtained before marketing.

### **V. Risk Warning**

#### **1. Uncertainty in Drug R&D**

Due to the special nature of drug R&D, the long cycle from clinical trials to production and launch, which involves many stages, is susceptible to many unpredictable factors, rendering the successful completion of product launch in the future uncertain.

## 2. Market Risk of the Drug

The drug to which the clinical approval has been granted is a drug in Category 2.2 and 2.4, which can provide patients with new medication options. However, since there are products of the same category available in the domestic market, there is uncertainty as to whether the Drug will gain a certain market share upon its launch in the future.

Based on the above, the grant of Approval Notice for Clinical Trial on Drug is not expected to generate sales revenue in the near future and will not have a material impact on the Company's results. The Company will fulfil its information disclosure obligations in a timely manner in accordance with the progress of R&D. Investors are advised to pay attention to investment risks.

Notice is hereby given.

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

**30 December 2021**

*\* For identification purpose only*