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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 OBTAINING APPROVAL NOTICE FOR CLINICAL TRIAL ON A 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
7 April 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. Zheng Zhihua, Mr. Xie Yun, Mr. Tian Qiusheng and Mr. Wong Kam Wa.

** For identification purpose only*

LIVZON PHARMACEUTICAL GROUP INC. ANNOUNCEMENT ON OBTAINING APPROVAL NOTICE FOR CLINICAL TRIAL ON A 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.

Livzon Pharmaceutical Group Inc.* (麗珠醫藥集團股份有限公司) (the “**Company**”) and its wholly-owned subsidiary Zhuhai Livzon Microsphere Technology Co. Ltd.* (珠海市麗珠微球科技有限公司) (“**Livzon Weiqiu**”) have recently obtained the "Approval Notice for Clinical Trial on Drug" which was approved and issued by the China National Medical Products Administration (“NMPA”). The relevant details are now disclosed as follows:

I. THE MAIN CONTENTS OF THE APPROVAL NOTICE FOR CLINICAL TRIAL ON DRUG

Chinese name: 注射用雙脛萘酸曲普瑞林微球

English/Latin name: Triptorelin Pamoate Microspheres for Injection

Dosage form: injection

Specification: 15mg

Application item: application for clinical trial

Registration classification: Class 2.2 chemical drug

Applicants: Livzon Pharmaceutical Group Inc. and Zhuhai Livzon Microsphere Technology Co. Ltd.

Review conclusion: It has been determined after review that the drug meets the relevant requirements for drug registration and is approved to proceed with clinical trials in accordance with the Pharmaceutical Administration Law of the People’s Republic of China and relevant regulations.

II. DRUG RESEARCH AND DEVELOPMENT AND RELATED CONDITIONS

The Triptorelin Pamoate Microspheres for Injection is a high-end long-acting microsphere preparation which has been researched and developed by the Company independently for six years. The first clinical trial application submitted was accepted on 20 January 2021 (acceptance No.: CXHL2100048).

The drug is a gonadotropin-releasing hormone agonist (促性腺激素釋放激素激動劑) for an intramuscular injection every three months, and is indicated for the treatment of locally advanced or metastatic prostate cancer. Compared with ordinary triptorelin injection, it has the characteristics of longer efficacy and reduced medication frequency, which can alleviate patients' pain and medication burden, as well as improve tolerance and accessibility of medication.

As at the date of this announcement, the accumulated direct investment expenses in research and development of the Triptorelin Pamoate Microspheres for Injection is approximately RMB14.9945 million.

III. MARKET CONDITIONS OF THE DRUG

According to the website of the CDE and Xanda Data, as at the date of this announcement, a total of three imported long-acting and controlled-release preparations of Triptorelin are marketed in China including two one-month preparations and one three-month preparation. There are currently no domestic manufacturers who have obtained manufacturing approvals and there are three manufacturers whose applications for clinical trials have been approved, including the Company's Triptorelin Acetate Microspheres for Injection and Triptorelin Pamoate Microspheres for Injection.

According to IQVIA sampling statistical estimates, the domestic sales to end customers of Triptorelin preparations in 2020 were approximately RMB1,024.8447 million, of which the domestic sales to end customers of long-acting and controlled-release preparations were approximately RMB880.9479 million (including one-month preparations and three-month preparations).

IV. APPROVAL PROCEDURES THAT STILL NEED TO BE FULFILLED FOR MARKETING

After the Company obtains the clinical approval for Triptorelin Pamoate Microspheres for Injection, it needs to conduct clinical trial in accordance with the content of the approval. It is initially estimated that it will take two to three years to complete the clinical trial and then an application for manufacturing and marketing shall be submitted and the approval of such application shall be obtained before marketing.

V. RISK WARNING

Due to the special nature of the research and development of drug, the long cycle from clinical trials to manufacturing and marketing which involves many stages, susceptibility to many unpredictable factors, coupled with 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. *

8 April 2021

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