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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 THE NEW INDICATION OF TRIPTORELIN 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
8 October 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 THE APPROVAL FOR THE NEW INDICATION OF TRIPTORELIN 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.

Recently, Livzon Pharmaceutical Group Inc.* (麗珠醫藥集團股份有限公司) (the “Company”) and its controlling subsidiary, Shanghai Livzon Pharmaceutical Manufacturing Co., Ltd.* (上海麗珠製藥有限公司) received the Drug Registration Certificate (Certificate No.: 2024S02341) issued by the National Medical Products Administration, which approved the registration of the new indication of “endometriosis” for Triptorelin Acetate Microspheres for Injection (注射用醋酸曲普瑞林微球) of the Company. The details are announced as follows:

I. THE MAIN CONTENTS OF THE DRUG REGISTRATION CERTIFICATE

Common name of the drug: Triptorelin Acetate Microspheres for Injection (注射用醋酸曲普瑞林微球)

English name/Latin Name: Triptorelin Acetate Microspheres for Injection

Dosage form: injection

Strength: 3.75mg (based on $C_{64}H_{82}N_{18}O_{13}$)

Application: drug registration (domestic production)

Registration classification: chemical drug, category 2.4

Marketing authorization holder: Livzon Pharmaceutical Group Inc.

Manufacturer: Shanghai Livzon Pharmaceutical Manufacturing Co., Ltd.

Drug approval number: NMPA H20230009

Approval conclusion: Pursuant to the Drug Administration Law of the People’s Republic of China and relevant regulations, it is determined after review that the drug meets the relevant requirements for drug registration, and is therefore approved for the new indication, which is “endometriosis”. The drug registration certificate is hereby issued.

II. RESEARCH AND DEVELOPMENT (“R&D”) OF THE DRUG AND RELEVANT INFORMATION

Triptorelin Acetate Microspheres for Injection is a high-end long-acting microsphere preparation independently developed by the Company, and was approved for market launch in May 2023. It is applicable to “prostate cancer patients who need androgen deprivation therapy”. For details, please refer to the ANNOUNCEMENT ON THE RECEIPT OF REGISTRATION APPROVAL FOR TRIPTORELIN ACETATE MICROSpheres FOR INJECTION (Announcement No.: 2023-037) issued by the Company on 11 May 2023.

The application for marketing authorization for Triptorelin Acetate Microspheres for Injection in relation to “endometriosis” was accepted on 23 August 2023. For details, please refer to the ANNOUNCEMENT ON THE ACCEPTANCE OF THE APPLICATION FOR MARKETING AUTHORIZATION FOR THE NEW INDICATION OF TRIPTORELIN ACETATE MICROSpheres FOR INJECTION (Announcement No.: 2023-072) issued by the Company on 25 August 2023.

The drug is a gonadotropin-releasing hormone agonist for an intramuscular injection every month. Compared with ordinary triptorelin acetate 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 in R&D expenses of Triptorelin Acetate Microspheres for Injection is approximately RMB132.6001 million.

III. MARKET CONDITIONS OF SIMILAR DRUGS

According to the website of the CDE and Xanda Data, as at the date of this announcement, there are two domestic manufacturers and a total of four imported long-acting and controlled-release preparations of Triptorelin that are marketed in China’s mainland (including Triptorelin Acetate for Injection (3.75mg), Triptorelin Pamoate for Injection (15mg), Triptorelin Pamoate for Injection (22.5mg) and Triptorelin for Injection (3.75mg)). Apart from the Company, there are currently no domestic manufacturers whose products have obtained manufacturing approvals.

According to IQVIA sampling statistical estimates, the total domestic sales of triptorelin preparations in 2023 were RMB1,403 million, of which the sales of the long-acting and controlled-release preparations were RMB1,225 million.

IV. IMPACT ON THE COMPANY AND RISK WARNING

The new indication of Triptorelin Acetate Microspheres for Injection has greatly expanded the application scope of the drug, further met clinical needs, and improved the market competitiveness of the drug. There are uncertainties in product operations which are susceptible to factors such as changes in market environment. Investors are advised to make prudent decisions and pay attention to investment risks.

Notice is hereby given.

Board of Directors of Livzon Pharmaceutical Group Inc. *

9 October 2024

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