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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 DRUG REGISTRATION CERTIFICATE” 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
15 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 DRUG REGISTRATION CERTIFICATE

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 MABPharm Inc.* (珠海市麗珠單抗生物技術有限公司) (“Livzon MAB”), a controlling subsidiary of Livzon Pharmaceutical Group Inc.* (麗珠醫藥集團股份有限公司) (the “Company”), received the “Drug Registration Certificate” (Certificate number: 2021S00375) issued by China National Medical Products Administration. The relevant details are now disclosed as follows:

I. MAIN CONTENT OF THE DRUG REGISTRATION CERTIFICATE

Generic name in Chinese: 注射用重組人絨促性素

English name/Latin name: Recombinant Human Choriogonadotropin alfa for Injection

Trade Name: 麗得寶

Main ingredient: Recombinant Human Choriogonadotropin α

Dosage form: injection

Strength: 250 μ g (6500 IU)/vial

Drug registration standard number: YBS00292021

Application: drug registration (domestic production)

Registration category: a therapeutic biological product

Shelf life: 24 months

Marketing authorization holder: Livzon MABPharm Inc.*

Drug manufacturer: Livzon Group Livzon Pharmaceutical Factory* (麗珠集團麗珠製藥廠)

Drug approval number: Guo Yao Zhun Zi S20210010

Expiry date of drug approval number: 12 April 2026

Approval conclusion: upon review, this product has fulfilled the relevant requirements of drug registration pursuant to the Drug Administration Law of the People's Republic of China (《中華人民共和國藥品管理法》) and relevant regulations, hence registration was approved and a drug registration certificate was issued. The production process, quality standards, instructions and labels shall be executed in accordance with the certificate as attached.

II. RESEARCH AND DEVELOPMENT AND RELEVANT INFORMATION OF THE DRUG

The Recombinant Human Choriogonadotropin alfa for Injection is a therapeutic biological product developed by Livzon MAB based on biosimilar. The clinical trial application for Recombinant Human Choriogonadotropin alfa for Injection submitted for the first time was accepted in December 2014 (acceptance No.: CXSL1400155 Yue), the approval for the clinical trials was obtained in September 2016 (approval No.: 2016L08624), and the production application was accepted in January 2019 (acceptance No.: CXSS1900006 Guo).

This product is suitable to: 1. women who receive superovulation prior to the assisted reproductive techniques such as in vitro fertilization (IVF), as its injection is used to trigger final follicular maturation and luteinization by stimulating follicular growth; and 2. women with anovulation or sporadic ovulation, as its injection is used to trigger ovulation and luteinization by stimulating follicular growth.

As at the date of this announcement, the accumulated investment expenses in research and development of the Recombinant Human Choriogonadotropin alfa for Injection is approximately RMB115.892 million.

III. MARKET CONDITIONS OF COMPARABLE DRUGS

Human chorionic gonadotropin is classified into urinary-derived human chorionic gonadotropin (u-hCG) and recombinant human chorionic gonadotropin (r-hCG) according to the source of its preparation. At present, Merck Serono's recombinant human chorionic gonadotropin drug is the sole product available for global sales under the trade name of Ovidrel® (Chinese name 艾泽®), which was approved for import to China in 2005.

According to the sampling statistics by IQVIA, the terminal sales of domestic human chorionic gonadotropin (including urine-derived and recombinant) amounted to approximately RMB138.4099 million in 2020, among which, the terminal sales of domestic recombinant human chorionic gonadotropin amounted to approximately RMB51.9579 million in 2020.

According to the website of the Center for Drug Evaluation, as at the date of this announcement, Livzon MAB is the only one that obtained the production approval for this drug in mainland China, without filings made by other manufacturers for clinical trial and production.

IV. APPROVAL PROCEDURES PENDING COMPLETION FOR MARKETING AND RISK WARNING

After obtaining the drug registration certificate, Livzon MAB may produce and market this product. The operation of the product is subject to uncertainties due to changes in the market environment and other factors. Investors are advised to make cautious decisions and pay attention to investment risks.

Notice is hereby given.

Board of Directors of Livzon Pharmaceutical Group Inc. *

16 April 2021

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