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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)

VOLUNTARY ANNOUNCEMENT

OBTAINMENT OF THE DRUG SUPPLEMENTARY APPLICATION APPROVAL NOTICE FOR LEUPRORELIN ACETATE MICROSPHERES FOR INJECTION 11.25MG (THREE-MONTH FORMULATION)

Recently, 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**”), received the Drug Supplementary Application Approval Notice (Notice No.: 2026B06648) approved and issued by the National Medical Products Administration of the People's Republic of China* (國家藥品監督管理局) (“**NMPA**”). Leuprorelin Acetate Microspheres for Injection 11.25mg (three-month formulation) (the “**Product**”) manufactured by Shanghai Livzon has been approved for marketing. The relevant particulars are announced as follows:

KEY PARTICULARS OF THE DRUG SUPPLEMENTARY APPLICATION APPROVAL NOTICE

Generic Name: Leuprorelin Acetate Microspheres for Injection

English/Latin name: Leuprorelin Acetate Microspheres for Injection

Dosage form: Injection

Specification: 11.25mg

Registration Classification: Chemical Drug

Marketing Authorization Holder: Shanghai Livzon Pharmaceutical Manufacturing Co., Ltd.

Manufacturer: Shanghai Livzon Pharmaceutical Manufacturing Co., Ltd.

Drug Registration Standard No.: YBH28982026

National Drug Approval Number: 國藥准字 H20269239

Validity Period of Approval Number: 27 April 2029

Approval conclusion: Upon examination in accordance with the Drug Administration Law of the People's Republic of China and relevant provisions, the current application in respect of the Product complies with the relevant requirements for drug registration. Approval is granted to add the 11.25mg specification to the Product, and a National Drug Approval Number is issued.

DRUG DEVELOPMENT AND RELATED CONDITIONS

Leuporelin Acetate Microspheres for Injection is a Category B drug under the National Drug Catalogue for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance. The indications of the three-month formulation are: (1) premenopausal breast cancer; (2) prostate cancer; and (3) central precocious puberty.

Leuporelin Acetate Microspheres for Injection (three-month formulation) is administered by subcutaneous injection once every 12 weeks. Unlike the marketed one-month formulation with a specification of 3.75mg, the three-month formulation differs in formulation process, quality standards, dosage and administration, and indications. The three-month formulation uses a completely different core excipient, poly (DL-lactide), and has the advantages of a longer duration of action and less frequent dosing. Following injection, it can maintain a stable blood drug concentration for 12 weeks and has a more stable release profile, substantially reducing fluctuations in blood drug concentration following repeated administration of the one-month formulation. It can reduce patients' pain and medication burden and improve medication tolerability and accessibility.

Poly (DL-lactide) is a polymer excipient independently developed by Shanghai Livzon and is the core excipient controlling the release of the microspheres. Following the associated review, the registration status of this excipient was changed to "A". Following PLGA7525, poly (DL-lactide) is the second polymer of the Company to be approved, further enhancing the Company's competitiveness in microsphere technology research and development.

As at the date of this announcement, the cumulative direct investment expenses in research and development for Leuporelin Acetate Microspheres for Injection (three-month formulation) amounts to approximately RMB94.0548 million.

MARKET LANDSCAPE OF SIMILAR DRUGS

As at the date of this announcement, Shanghai Livzon is the only company in China holding an approval for Leuporelin Acetate Microspheres for Injection (three-month formulation), excluding the originator product. According to IQVIA sampling statistical estimates, the domestic terminal sales value of long-acting GnRHa sustained-release formulations in China in 2025 was approximately RMB10.9 billion, of which three-month long-acting GnRHa sustained-release formulations accounted for 27%.

IMPACT ON THE COMPANY AND RISK WARNING

According to enquiries conducted by the Company, the Company's Leuporelin Acetate Microspheres for Injection (three-month formulation) is the world's first gonadotropin-releasing hormone ("GnRH") preparation approved following completion of a bioequivalence study conducted in accordance with the product-specific guidance of the United States Food and Drug Administration ("FDA"). The approval of the Product fills the technological gap in three-month long-acting sustained-release microsphere formulations in China. The Company's Leuporelin Acetate Microspheres for Injection has now been approved in three specifications, namely 3.75mg, 1.88mg and 11.25mg, achieving full coverage of the specifications of domestically produced Leuporelin Acetate Microspheres for Injection. This can meet the needs of different treatment cycles and individualized medication for patients and further consolidate the Company's leading position in the research and development of microsphere formulations in China. Pharmaceutical products are characterized by high technology, high risks and high added value, and the sales of drugs are susceptible to numerous unpredictable factors, including national policies and the market environment, and are subject to uncertainties. Investors are advised to exercise caution when making investment decisions and to pay attention to investment risks.

By order of the Board
Livzon Pharmaceutical Group Inc.*
麗珠醫藥集團股份有限公司
Liu Ning
Company Secretary

Zhuhai, China
29 September 2026

As at the date of this announcement, the executive directors of the Company are Mr. Liu Daping (Chairman and President) and Mr. Tang Yanggang (Vice Chairman); the non-executive directors of the Company are Mr. Lin Nanqi and Mr. Qiu Qingfeng; the employee representative director of the Company is Ms. Ran Yongmei; and the independent non-executive directors of the Company are Mr. Luo Huiyuan, Ms. Cui Lijie, Ms. Wang Zhiyao and Ms. Kang Li.

** For identification purpose only*