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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 REGISTRATION CERTIFICATE FOR RECOMBINANT HUMAN FOLLITROPIN ALFA SOLUTION FOR INJECTION

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 No.: 2026S01827) approved and issued by the National Medical Products Administration of the People's Republic of China ("**NMPA**"). The relevant particulars are announced as follows:

KEY PARTICULARS OF THE DRUG REGISTRATION CERTIFICATE

Generic Name: Recombinant Human Follitropin Alfa Solution for Injection

English/Latin name: Recombinant Human Follitropin Alfa Solution for Injection

Trade Name: 麗優寶

Main Ingredient: Recombinant Human Follitropin Alfa

Dosage form: Injection

Specification: Pre-filled pen: 33 μg (450 IU)/0.75 mL

Drug Registration Standard No.: YBS00552026

Application Matter: Drug registration (domestic manufacturing)

Registration Classification: Class 3.3 Therapeutic Biological Product

Shelf Life: 24 months

Marketing Authorization Holder: Livzon MABPharm Inc.

Manufacturer: Livzon Group Livzon Pharmaceutical Factory

National Drug Approval Number: 國藥准字 S20260035

Validity Period of Approval Number: 26 May 2031

Approval conclusion of the Acceptance Notice: Upon examination in accordance with the Drug Administration Law of the People's Republic of China and relevant provisions, the Product complies with the requirements for drug registration. Approval is granted for registration, and the Drug Registration Certificate is issued. The manufacturing process, quality standards, specifications and labels shall be implemented as attached.

DRUG DEVELOPMENT AND RELATED CONDITIONS

Recombinant Human Follitropin Alfa Solution for Injection (the "**Product**") is independently developed by Livzon MAB. The indications applied for in this registration are as follows: (i)Anovulation (including polycystic ovary syndrome ("**PCOS"**)) in women who are unresponsive to clomiphene citrate therapy. (ii)Ovarian hyperstimulation in women undergoing assisted reproductive technology ("**ART**") such as in vitro fertilization and embryo transfer ("**IVF**"), gamete intrafallopian transfer ("**GIFT**") and zygote intrafallopian transfer ("**ZIFT**"), to stimulate multiple follicular development. (iii)Patients with severe deficiency of luteinizing hormone ("**LH**") and follicle-stimulating hormone ("**FSH**"), i.e., patients with endogenous serum LH levels <1.2 IU/L. Combined use of LH and FSH is recommended to stimulate follicular development.

Manufactured using recombinant gene technology with a stable and controllable process, the Product is administered via an injection pen, enhancing patients' user experience and treatment compliance. The Product has completed Phase I to III clinical evaluations as a biosimilar. The data demonstrate that it is equivalent to the comparable drugs in terms of efficacy, safety, immunogenicity and pharmacokinetics ("**PK**"). Adopting advanced manufacturing processes and rigorous analytical techniques, the Product ensures safety and purity, as well as safeguarding patients' medication safety.

As at the date of this announcement, the cumulative direct investment expenses in research and development for Recombinant Human Follitropin Alfa Solution for Injection amounts to approximately RMB121.69 million.

MARKET LANDSCAPE OF COMPARABLE DRUGS

According to databases of the NMPA and the Center for Drug Evaluation ("**CDE**"), as of the date of this announcement, there are four imported products and four domestic products of Recombinant Human Follitropin Alfa Solution for Injection marketed in China.

Currently, the incidence of reproductive disorders such as infertility in China is increasing year by year, with a younger patient demographic. As a commonly used drug in assisting reproduction, market demand for the Product will continue to grow. According to IQVIA sampling statistical estimation, the domestic terminal sales value of FSH drugs in 2025 was approximately RMB2.541 billion, and the domestic terminal sales value of FSH drugs from January to March 2026 was approximately RMB0.538 billion, of which Recombinant Human Follitropin Alfa drugs account for more than 56%.

IMPACT ON THE COMPANY AND RISK WARNING

After obtaining the Drug Registration Certificate, the Company can manufacture and market the Product. However, the operating performance of the Product is subject to uncertainties due to factors such as changes in the market environment. 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
1 June 2026

As at the date of this announcement, the executive directors of the Company are Mr. Liu Daping (President) and Mr. Tang Yanggang (Vice Chairman); the non-executive directors of the Company are Mr. Zhu Baoguo (Chairman), 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*