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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 CLINICAL TRIAL APPROVAL NOTICE FOR RECOMBINANT HUMANIZED ANTI-FXI BISPECIFIC ANTIBODY INJECTION

Recently, Livzon MABPharm Inc. (珠海市麗珠單抗生物技術有限公司) (“**Livzon MAB**”), a subsidiary of Livzon Pharmaceutical Group Inc.* (麗珠醫藥集團股份有限公司) (the “**Company**”), received the Drug Clinical Trial Approval Notice (Notice No.: 2026LP03262) 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**”), approving the conduct of clinical trials of Recombinant Humanized Anti-FXI Bispecific Antibody Injection (the “**Product**”) applied for by Livzon MAB for the indication of prevention of venous thromboembolism following total knee arthroplasty. The relevant particulars are announced as follows:

BASIC INFORMATION OF THE DRUG

Generic Name: Recombinant Humanized Anti-FXI Bispecific Antibody Injection

Dosage form: Injection

Registration Classification: Class 1 therapeutic biological product

Proposed indication: Prevention of venous thromboembolism following total knee arthroplasty

Applicant: Livzon MABPharm Inc.

Approval conclusion: Upon examination in accordance with the Drug Administration Law of the People's Republic of China and relevant provisions, Recombinant Humanized Anti-FXI Bispecific

Antibody Injection, the application for which was accepted on 5 August 2026, complies with the relevant requirements for drug registration, and approval is granted to conduct clinical trials.

DRUG DEVELOPMENT AND RELATED CONDITIONS

LZSN2501 is a recombinant humanized biparatopic bispecific antibody targeting coagulation factor XI (FXI). The indication for this clinical trial application is prevention of venous thromboembolism following total knee arthroplasty.

For patients following total knee arthroplasty, currently mainstream anticoagulants generally carry varying degrees of bleeding risk, and FXI/FXIa inhibitors represent an important research and development direction for next-generation anticoagulants. The clinical trial approved on this occasion is a single-dose, dose-escalation Phase I clinical study to evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic profiles of the Product in healthy adult participants in China. In postoperative anticoagulation therapy, balancing thrombosis prevention and control with haemostatic safety is critical. The Product adopts a biparatopic bispecific antibody design that enables it to bind simultaneously to the A2 domain and the catalytic domain of FXI, exerting anticoagulant effects at two stages by inhibiting FXI activation and the enzymatic activity of FXIa. Preliminary non-clinical studies have shown that the Product has a clear antithrombotic effect with limited impact on normal haemostasis, suggesting the potential for a safety advantage in this indication. Based on the above molecular design and non-clinical study results, the Product is expected to offer a next-generation anticoagulation treatment option that balances antithrombotic efficacy and haemostatic safety, further enriching the Company's pipeline in anticoagulation therapy.

The Company obtained the candidate molecule and related patent rights through the introduction of the project and, on this basis, completed subsequent development work, including cell line construction, pharmaceutical research, non-clinical studies, clinical protocol design and preparation of the investigational new drug (IND) application dossier.

As at the date of this announcement, the cumulative direct investment expenses in research and development for the Product amount to approximately RMB28.2396 million.

RISK WARNING

Under the relevant laws and regulations governing drug registration in China, after obtaining the Drug Clinical Trial Approval Notice, a drug must still undergo clinical trials and pass the review and approval of the NMPA before it can be manufactured and marketed. Given the particular nature of drug research and development, the process from clinical trials to production and marketing is lengthy, involves multiple stages and is susceptible to numerous unpredictable factors. There are therefore various uncertainties regarding the progress and results of clinical trials and the future market competition for the product. The Company will fulfil its information disclosure obligations in a timely manner in accordance with the progress of research and development. Investors are advised 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
27 October 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*