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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

ACCEPTANCE OF APPLICATION FOR REGISTRATION AND MARKETING AUTHORIZATION OF JP-1366 TABLETS

Recently, Livzon Pharmaceutical Group Inc.* 麗珠醫藥集團股份有限公司 ("**the Company**") has received the Acceptance Notification (Acceptance No.: CYHS2502991) approved and issued by the National Medical Products Administration ("**NMPA**") in respect of the Company's application for domestic production and drug registration of JP-1366 tablets (the "**Product**"). The details are announced as follows:

I. PRINCIPAL CONTENTS OF THE ACCEPTANCE NOTIFICATION

Drug Name: JP-1366 tablets (JP-1366片)

English Name/Latin Name: JP-1366 tablets

Dosage Form: Tablet

Specification: 20mg

Indication: Reflux esophagitis

Application Item: Domestic production, drug registration and marketing authorization

Applicant: Livzon Pharmaceutical Group Inc.*

Approval Conclusion: In accordance with the provisions of Article 32 of the Administrative Licensing Law of the People's Republic of China (《中華人民共和國行政許可法》), after review, it is decided to accept the application.

II. DRUG R&D AND RELEVANT INFORMATION

JP-1366 tablets is an innovative potassium-competitive acid blocker (P-CAB). It can competitively block the K(+) channel of H(+), K(+)-ATPase (proton pump), inhibit the binding of K(+) to the proton pump, and suppress gastric acid secretion, thereby promoting the healing of esophageal mucosa and alleviating reflux symptoms. JP-1366 tablets can increase the intragastric pH value at a relatively fast rate and maintain the intragastric pH value＞4 for a prolonged period, which can effectively address nocturnal acid breakthrough.

The Company has initiated a multicenter, randomized, double-blind, positive parallel-controlled phase III clinical trial to compare JP-1366 tablets with Nexium® (Esomeprazole Magnesium Enteric-coated Tablets) in Chinese patients with reflux esophagitis. The first subject was enrolled in December 2024, and the last visit of the last subject was completed in June 2025. A total of 362 Chinese patients with reflux esophagitis were included in the trial. The results confirmed that the esophageal mucosal healing rate of JP-1366 tablets within 8 weeks after administration is non-inferior to that of Nexium®. Meanwhile, JP-1366 tablets could notably alleviate symptoms such as heartburn and reflux. Based on the results of the phase III clinical trial, the Company has submitted a marketing authorization application for the indication of reflux esophagitis of JP-1366 tablets to the Center for Drug Evaluation of the National Medical Products Administration ("**CDE**").

For information on the approval of the clinical trial of the Product for reflux esophagitis, please refer to the Company's Announcement on Obtaining the Drug Clinical Trial Approval Notification (Announcement No.: 2024-011) published on 23 February 2024 on Cninfo website. The research and development progress of the Product shall be subject to the announcements published by the Company on statutory information disclosure newspapers and websites.

JP-1366 for injection with the same molecule developed by the Company is in phase I clinical trial stage, with the indication of peptic ulcer bleeding. Currently, there is no injection of P-CAB drugs available on the global market.

As at the date of disclosure of the announcement, the cumulative direct R&D investment in JP-1366 tablets is approximately RMB185.2082 million.

III. MARKET CONDITIONS OF THE DRUG

In China's clinical guidelines, proton pump inhibitors (PPIs) and potassium-competitive acid blockers (P-CABs) are recommended as first-line treatment options for gastroesophageal reflux disease. According to the estimated data based on sample statistics from IQVIA, the domestic terminal sales amount of P-CAB in 2024 was approximately RMB1,248.1214 million, representing a year-on-year increase of 81.22% compared with 2023; the domestic terminal sales amount in the first quarter of 2025 was approximately RMB394.3468 million, representing a year-on-year increase of 81.63% compared with the first quarter of 2024. JP-1366 tablets will further enrich the Company's product pipeline in the gastrointestinal field, providing more comprehensive treatment options for clinical practice.

IV. RISK WARNING

In accordance with the relevant laws and regulations on national drug registration, after the registration application of JP-1366 tablets accepted by the NMPA, it will be transferred to the CDE for review and approval. The time for completion and the approval result are subject to uncertainty. The Company will timely perform its information disclosure obligations in accordance with subsequent developments. Investors are kindly advised to make prudent decisions and 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
15 August 2025

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. Lin Nanqi and Mr. Qiu Qingfeng; 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*