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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

ACHIEVEMENT OF THE PRIMARY ENDPOINT IN PHASE III CLINICAL TRIAL OF RECOMBINANT ANTI-HUMAN IL-17A/F HUMANIZED MONOCLONAL ANTIBODY INJECTION

Recently, Recombinant anti-human IL-17A/F Humanized Monoclonal Antibody Injection (重組抗人 IL-17A/F 人源化單克隆抗體注射液) (“LZM012” or the “Drug”), jointly developed by Livzon MABPharm Inc.* (珠海市麗珠單抗生物技術有限公司) (“Livzon MAB”), which is a controlling subsidiary of Livzon Pharmaceutical Group Inc.* (麗珠醫藥集團股份有限公司) (the “Company”), and Beijing Kanova Biopharmaceutical Co., Ltd.* (北京鑫康合生物醫藥科技有限公司) has achieved the primary endpoint of phase III clinical trial. Details are as follows:

I. MAIN CONTENTS OF THE DRUG

Drug name: 重組抗人 IL-17A/F 人源化單克隆抗體注射液

English/Latin name: Recombinant anti-human IL-17A/F Humanized Monoclonal Antibody Injection

Dosage form: injection

Strength: 160 mg (1.6 mL)/Vial

Category of registration: Class 1 of therapeutic biological products

Applicant for market launch: Livzon MABPharm Inc.*

II. CLINICAL TRIAL RELATED INFORMATION

The phase III clinical study is a multi-center, randomized, double-blind, active-controlled (secukinumab) clinical trial conducted in patients with moderate-to-severe plaque psoriasis. The leading unit of the clinical trial is Huashan Hospital affiliated to Fudan University (復旦大學附屬華山醫院).

The primary endpoint of phase III clinical trial is the proportion of subjects achieving a Psoriasis Area and Severity Index (PASI) 100 response (PASI 100 response rate) at week 12. The study results showed that the primary efficacy endpoint of the study was achieved. The PASI 100 response rate at week 12 was 49.5% for LZM012 and 40.2% for secukinumab control group, indicating that LZM012 is non-inferior to secukinumab and superior to secukinumab. As for the major secondary efficacy endpoints, the PASI 75 response rate at week 4 was 65.7% for LZM012 and 50.3% for secukinumab control group, indicating that LZM012 has a faster onset of action; the PASI 100 response rates at week 52 for the LZM012 320mg Q4W and 320mg Q8W maintenance treatment groups were 75.9% and 62.6%, respectively, indicating a sustained boost in benefit for patients with psoriasis. In terms of safety, the overall safety profile of the Drug is favorable, with the incidence of common adverse events comparable to that of the control group for various adverse events.

For LZM012 in the treatment of moderate-to-severe plaque psoriasis indication in adults, the Company has recently submitted to the Center for Drug Evaluation (“CDE”) of the National Medical Products Administration an application for communication prior to application for market launch, to advance the marketing process of LZM012.

III. DRUG RELATED INFORMATION

Jointly developed by Livzon MAB and Beijing Kanova Biopharmaceutical Co., Ltd.*, LZM012 obtained the clinical trial approval for moderate-to-severe plaque psoriasis indication on 19 February 2020 (application number: CXSL1900130). For details of the approval of clinical trial application of the Drug, please refer to the “ANNOUNCEMENT ON THE APPROVAL OF APPLICATION FOR CLINICAL TRIAL ON A NEW DRUG” (Announcement No.: 2020-011) published by the Company on 20 February 2020 on Cninfo website* (巨潮資訊網).

IV. RISK WARNING

The Drug is subject to subsequent completion of procedures such as communication with CDE, submission of new drug market launch application, technical review and on-site verification.

Due to the special nature of drug research and development, the cycle from clinical trials to production and market launch is long and involves many stages, which may be affected by numerous unpredictable factors. The Company will fulfill its information disclosure obligations in a timely manner based on the progress of subsequent developments, and 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
21 July 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*