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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)

Overseas Regulatory Announcement

This announcement is made pursuant to Rule 13.10B of the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited.

Set out below is the “ANNOUNCEMENT ON OBTAINING DRUG REGISTRATION CERTIFICATE” of Livzon Pharmaceutical Group Inc.* published on the website of the Shenzhen Stock Exchange, which is set out herein for information purpose only.

The abovementioned announcement is prepared in Chinese, if there is any discrepancy between the Chinese version and the English version, the Chinese version shall prevail.

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

Zhuhai, China
23 October 2020

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. Qiu Qingfeng and Mr. Yu Xiong; and the Independent Non-Executive Directors of the Company are Mr. Bai Hua, Mr. Zheng Zhihua, Mr. Xie Yun, Mr. Tian Qiusheng and Mr. Wong Kam Wa.

** For identification purpose only*

LIVZON PHARMACEUTICAL GROUP INC. ANNOUNCEMENT ON OBTAINING DRUG REGISTRATION CERTIFICATE

The Company and all members of the Board of Directors guarantee all contents of the disclosed information are true, accurate and complete, and no false representation, misleading statement or material omission is made.

Recently, Livzon Group Livzon Pharmaceutical Factory* (the “Livzon Pharmaceutical Factory”), a wholly-owned subsidiary of 麗珠醫藥集團股份有限公司 Livzon Pharmaceutical Group Inc.* (the “Company”), received the “Drug Registration Certificate” (Certificate number: 2020S00668) issued by National Medical Products Administration. The relevant status is announced as follows:

I. Main Content of the Drug Approval

Generic name of the drug: Dantrolene Sodium for Injection (注射用丹曲林钠)

English name/Latin name: Dantrolene Sodium for Injection

Dosage form: injection

Strength: 20mg

Application: drug registration (domestic production)

Registration category: category 3 chemicals

Shelf life of drug: 12 months

Holder of production approval: Livzon Group Livzon Pharmaceutical Factory*

Manufacturer: Livzon Group Livzon Pharmaceutical Factory*

Drug approval number: Guo Yao Zhun Zi H20203530

Approval conclusion: upon review, this product fulfilled the relevant requirements of drug registration pursuant to the Pharmaceutical Administration Law of the People’s Republic of China and relevant regulations, hence registration was approved, and a drug registration certificate was issued.

II. Research and Development of the Drug and Relevant Status

Dantrolene Sodium for Injection have undergone 10 years of research and development. It is a generic drug independently developed by the Company and is indicated for the prevention and treatment of malignant hyperthermia. Malignant hyperthermia is a rare disease, and is a family hereditary myopathy which is mainly an abnormally high metabolic status of skeletal muscle triggered by volatile inhalation anesthetics and depolarizing muscle relaxants - Succinylcholine. In the absence of specific treatment

drugs, general clinical cooling measures can hardly control the increase in body temperature, which can eventually lead to patient death.

This product is the first generic drug in mainland China. The date of acceptance of the production application firstly submitted by Livzon Pharmaceutical Factory for this product is 1 February 2019 (acceptance number: CYHS1900135Guo).

As at the date of this announcement, total research and development expenses directly devoted to Dantrolene Sodium for Injection were approximately RMB17.2234 million.

III. Market Conditions of Comparable Drugs

The patent medicine of Dantrolene Sodium for Injection is Dantrium® by Par Sterile Products LLC from the U.S., which was firstly approved for production in the U.S. in 1979 for the use of controlling explosive hypermetabolism of skeletal muscle with malignant hyperthermia under applicable supportive treatments among different age ranges. According to the website of the Center for Drug Evaluation and the Xianda Database (咸達數據庫), as at the date of this announcement, Livzon Pharmaceutical Factory is the only one that obtained the registration approval for Dantrolene Sodium for Injection in mainland China, without filings made by other manufacturers.

IV. Risk Alert

After obtaining the drug registration approval, Livzon Pharmaceutical Factory may produce and market this product. The operation of the product is subject to uncertainties due to changes in the market environment and other factors. Investors are advised to make cautious decisions and pay attention to investment risks.

Notice is hereby given.

Board of Directors of Livzon Pharmaceutical Group Inc. *

24 October 2020

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