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CSPC PHARMACEUTICAL GROUP LIMITED

石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock code: 1093)

VOLUNTARY ANNOUNCEMENT

BIOLOGIC LICENSE APPLICATION FOR JMT103 ACCEPTED BY THE NMPA

The board of directors (the “**Board**”) of CSPC Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that the biologic license application (“**BLA**”) for the class 1 new drug JMT103 (Narlumosbart for Injection) (the “**Product**”) developed by Shanghai JMT-Bio Technology Co., Ltd.* (上海津曼特生物科技有限公司), a subsidiary of the Company, has been accepted by the National Medical Products Administration (NMPA) of the People’s Republic of China, and the Center for Drug Evaluation has agreed to the submission of application for priority review. At present, the application is in progress. The indication for this application is for the treatment of unresectable or surgically difficult giant cell tumor of bone.

The Product is the first IgG4 subtype fully human monoclonal antibody against RANKL filing BLA in the world. At present, denosumab, an IgG2 subtype, is the only marketed drug against the same target in the world. Compared with denosumab, the Product has significant enhancement in uniformity and quality controllability. Subcutaneous injection is used to administer the Product. It can block the binding of RANKL to the membrane RANK receptors of cells such as osteoclast precursor cells, osteoclasts and osteoclast-like giant cells so as to inhibit the differentiation, maturation and functional activity of the above cells mediated by RANKL-RANK signaling pathway. It is expected to treat diseases associated with the activation of RANKL-RANK signaling pathway, such as giant cell tumor of bone, osteoporosis, tumor bone metastasis.

The BLA for JMT103 is mainly based on two pivotal clinical studies in the treatment of unresectable or surgically difficult giant cell tumor of bone. The clinical studies demonstrated that JMT103 had a better clinical efficacy in the treatment of unresectable or surgically difficult giant cell tumor of bone with a tumor response rate of 93.5%, and a trend higher than that of the denosumab group. At the same time, JMT103 showed a good safety profile with controllable safety risks.

This application is the BLA for the first indication of the Product. Meanwhile, there are also other indications under development, including tumor bone metastasis and osteoporosis.

By order of the Board
CSPC Pharmaceutical Group Limited
Cai Dongchen
Chairman

Hong Kong, 22 June 2022

As at the date of this announcement, the Board comprises Mr. CAI Dongchen, Mr. ZHANG Cuilong, Mr. WANG Zhenguo, Mr. PAN Weidong, Mr. WANG Huaiyu, Dr. LI Chunlei, Dr. WANG Qingxi, Mr. CHAK Kin Man and Dr. JIANG Hao as executive directors; and Mr. WANG Bo, Mr. CHEN Chuan, Prof. WANG Hongguang, Mr. AU Chun Kwok Alan, Mr. LAW Cheuk Kin Stephen and Ms. WU Guizhen as independent non-executive directors.

** for identification purposes only*