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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 NARLUMOSBART FOR INJECTION (JMT103) APPROVED 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 class 1 new drug Narlumosbart for Injection (brand name: Jinlitai (津立泰)) (JMT103) (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, for the treatment of giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity has been approved by the National Medical Products Administration (NMPA) of the People’s Republic of China.

The Product is the first IgG4 subtype fully human monoclonal antibody against RANKL obtaining marketing approval in the world. At present, denosumab, an IgG2 subtype, is another 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, thereby inhibiting 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 granting of marketing approval for this new drug is mainly based on two pivotal clinical studies (JMT103CN03 Phase II Pivotal Clinical Study and JMT103CN03-1 Real-World Study) in the treatment of unresectable or surgically difficult giant cell tumor of bone. The clinical studies demonstrated that JMT103 has a better clinical efficacy in the treatment of unresectable or surgically difficult giant cell tumor of bone with a tumor response rate of 93.3%, 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 marketing approval is for the first indication of the Product. At present, 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, 6 September 2023

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. LI Quan as independent non-executive directors.