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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**

#### **CLASS 1 NEW DRUG JMT103 MEETS PRE-DEFINED ENDPOINTS IN THE PIVOTAL CLINICAL TRIAL FOR THE TREATMENT OF UNRESECTABLE OR SURGICALLY DIFFICULT GIANT CELL TUMOR OF BONE**

The board of directors (the “**Board**”) of CSPC Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that class 1 new drug JMT103 of 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 met its pre-defined endpoints in the pivotal clinical trial for the treatment of unresectable and surgically difficult giant cell tumor of bone.

JMT103 is an innovative fully human RANKL monoclonal antibody, with the affinity enhanced and manufacturing process simplified by optimising the structure of the co-targeted drug denosumab. Two clinical trials (JMT103CN03 and JMT103CN03-1) were conducted by the Group in China as pivotal clinical trials of JMT103 for the treatment of unresectable or surgically difficult giant cell tumor of bone, and were used to support the application for marketing approval of the product.

The JMT103CN03 study is a Phase II single-arm pivotal registration clinical study evaluating the efficacy and safety of JMT103 in the treatment of patients with unresectable or surgically difficult giant cell tumor of bone. A total of 139 subjects with giant cell tumor of bone were enrolled in the entire study and the primary efficacy endpoint for this study is the tumor response rate (based on histological response and imaging assessment results within 12 weeks).

The JMT103CN03-1 study is a retrospective study based on real-world data. This study collected clinical data from real-world medical settings of patients with unresectable or surgically difficult giant cell tumor of bone treated with denosumab or non-denosumab respectively as two external control groups for comparing the efficacy of the JMT103 single-arm trial group with that of the two external control groups in conjunction with the results of the JMT103CN03 study.

The results of the JMT103CN03 study demonstrated that JMT103 had good clinical efficacy in treating unresectable or surgically difficult giant cell tumor of bone, with tumor response rate of 93.5% and a faster onset of action; the proportion of patients with resectable giant cell tumor of bone increased after the therapy; patients with giant cell tumor of bone experienced relief in pain with improved quality of life. The results of the JMT103CN03-1 study demonstrated that JMT103 had a significantly better tumor response rate than the non-denosumab group, while demonstrated a trend higher than that of the denosumab group. Moreover, JMT103 demonstrated favorable tolerability. Based on the above study results, the Group has submitted an application for pre-marketing communication to the National Medical Products Administration of the People's Republic of China.

The Group possesses the intellectual property rights of JMT103, which has been patented in the PRC (including Hong Kong and Macau). The RANKL targeting drugs have shown promising market prospects globally in 2021, and according to publicly available financial reports from Amgen Inc., the 2021 global sales of denosumab, a drug with the same target, was US\$5.26 billion.

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

Hong Kong, 21 March 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 and Mr. LAW Cheuk Kin Stephen as independent non-executive directors.*

*\* For identification purpose only*