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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

CLINICAL DATA OF ALMB-0168 FOR THE TREATMENT OF OSTEOSARCOMA TO BE PRESENTED AT THE 2023 ASCO ANNUAL MEETING

The board of directors (the "Board") of CSPC Pharmaceutical Group Limited (the "Company", together with its subsidiaries, the "Group") is pleased to announce that AlaMab Therapeutics Inc., a subsidiary of the Company, will present the preliminary positive results on efficacy and safety of a Phase I clinical trial of ALMB-0168 in patients with osteosarcoma at the upcoming 2023 ASCO annual meeting taking place on 2-6 June 2023, titled "ALMB-0168, a novel Cx43 hemichannel agonist monoclonal antibody, for metastatic or unresectable osteosarcoma after standard chemotherapy: A multicenter, open-label, single-arm, phase I study".

Osteosarcoma is the most common primary malignant bone tumor which affects mostly adolescents (under 20 years old). However, the treatment of metastatic or unresectable osteosarcoma after standard chemotherapy remains a significant clinical challenge. ALMB-0168 is a first-in-class antibody agonist for novel drug target connexin 43 (Cx43) hemichannels and has been shown to suppress the growth and migration of osteosarcoma and breast cancer bone metastases in preclinical studies. ALMB-0168 has also been granted Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPD) by the U.S. Food and Drug Administration for treatment of osteosarcoma.

The study is a multicenter, open-label, single-arm Phase 1 clinical trial to evaluate the safety, tolerability, and preliminary efficacy of ALMB-0168 for treatment of osteosarcoma. The trial enrolled patients of ≥ 16 years with histologically confirmed osteosarcoma who progressed after standard chemotherapy.

A total of 13 patients were evaluable for response. The overall response rate (ORR) was 15.4% (2/13, 95% CI: 1.9-45.5%), including 2 partial responses (PR), 1 patient each at 6mg/kg and 18mg/kg. The patient at 6 mg/kg, who had ≥3 prior lines of therapy and lung metastases, achieved durable disease control with stable disease (SD) for 33 weeks followed by PR for 8+ weeks (at the time of analysis). The disease control rate (DCR) was 53.8% (7/13, 95% CI: 25.1-80.8%) with 2 PRs and 5 SDs. No dose-limiting toxicities, Cx43-related cardiac events or severe hepatic events were observed.

In conclusion, ALMB-0168 demonstrated encouraging efficacy and tolerable safety in patients with metastatic or unresectable osteosarcoma after standard chemotherapy in the Phase I dose-escalation trial.

By Order of the Board

CSPC Pharmaceutical Group Limited

CAI Dongchen

Chairman

Hong Kong, 30 May 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.