CSPC PHARMACEUTICAL GROUP LIMITED
石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock code: 1093)

VOLUNTARY ANNOUNCEMENT

ENLONSTOBART INJECTION OBTAINS CONDITIONAL MARKETING APPROVAL GRANTED BY 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 Enlonstobart Injection (brand name: Enshuxing) (the "**Product**"), a new Class 1 therapeutic biological product developed by the Group, has obtained conditional marketing approval granted by the National Medical Products Administration (NMPA) of the People's Republic of China.

The Product is a recombinant fully human anti-PD-1 monoclonal antibody, belonging to IgG4 monoclonal antibody drug. By targeting human programmed cell death protein-1 (PD-1), it reverses the PD-1 pathway-mediated immunosuppressive response, thereby activating the body's anti-tumor immune response. The approved indication of the Product is for the treatment of recurrent or metastatic cervical cancer patients with positive PD-L1 (CPS≥1) expression who have previously failed to respond to platinum-based chemotherapy. The approval is mainly based on a pivotal phase II clinical trial. The enrolled patients were recurrent or metastatic cervical cancer patients with positive PD-L1 expression who have failed to respond to at least first-line platinum-based chemotherapy previously (36.5% of them had previously received ≥2 lines of systemic therapy). The results showed that the Product significantly improved the objective response rate (ORR) in the treatment of advanced cervical cancer. The ORR assessed by the independent imaging review committee reaches 29%, including 2 cases of complete response and 29 cases of partial response, with a median duration of response of 16.6 months. Additionally, the Product has a good safety profile.

This is the first approved indication for the Product. Currently, a phase III clinical trial is in progress to evaluate the use of enlonstobart in combination with platinum-based chemotherapy, with or without bevacizumab, for the first-line treatment of recurrent or metastatic cervical cancer patients with positive PD-L1 (CPS≥1) expression. In addition, multiple clinical trials of the Product in combination with nanomedicines, antibody drugs/antibody-drug conjugates, small molecule drugs and other therapies self-developed by the Group for the treatment of different solid tumors are also being conducted simultaneously.

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

Hong Kong, 28 June 2024

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. JIANG Hao, Dr. YAO Bing and Mr. CAI Xin 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.