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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

ANTIBODY-DRUG CONJUGATE CPO301 OBTAINS CLINIAL TRIAL APPROVAL IN THE U.S.

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 antibody-drug conjugate CPO301 developed by the Group has obtained approval of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) to conduct clinical trial in the U.S.

The study is a multicenter, dose-escalation and dose-expansion Phase I clinal trial to evaluate the safety, pharmacokinetics and preliminary efficacy of CPO301 for the treatment of advanced lung cancer with alterations in the EGFR gene or EGFR over-expression.

Lung cancer is the leading cause of cancer incidence and mortality worldwide. Each year, it is estimated that there are more than 2.2 million new cases of lung cancer and more than 1.7 million deaths from lung cancer globally. EGFR activating mutation is one of the major drivers in lung cancer and has been the target for many approved EGFR tyrosine kinase inhibitors (TKIs), including a series of first-, second- and third-generation TKIs such as osimertinib. However, the emergence of new mutations after treatment with TKIs constitute a therapeutic challenge. For instance, new mutations emerge after osimertinib treatment in up to approximately 25% of non-small cell lung cancer patients, which leave no effective therapeutic treatments other than salvage chemotherapies.

Preclinical studies showed that CPO301 dose dependently inhibited the growth of human tumors with various EGFR-activating mutations or high expression of wild type EGFR models in immunodeficient mice. In particular, CPO301 showed potent anti-tumor efficacy in a human non-small cell lung cancer (NSCLC) PDX model harboring EGFR triple mutations (Exon19Del, T790M and C797S) that are

resistant to the third-generation EGFR-TKI osimertinib. CPO301 also demonstrated acceptable safety and tolerability in preclinical toxicology and safety pharmacology studies. These data support the fast-track development for CPO301 for the treatment of late line setting of NSCLC.

By order of the Board
CSPC Pharmaceutical Group Limited
Cai Dongchen

Chairman

Hong Kong, 3 April 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.