CSPC PHARMACEUTICAL GROUP LIMITED
石藥集團有限公司

(Incorporated in Hong Kong with limited liability)
(Stock code: 1093)

VOLUNTARY ANNOUNCEMENT

CPO301 WAS GRANTED FAST TRACK DESIGNATION BY THE U.S. FDA

The board of directors (the "**Board**") of CSPC Pharmaceutical Group Limited (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce that CPO301, a first-in-class antibody drug conjugate developed by the Group, has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the treatment of metastatic non-small cell lung cancer (NSCLC) patients with EGFR mutations who are relapsed/refractory to or ineligible for EGFR targeting therapy such as 3rd-generation EGFR inhibitors including Osimertinib.

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 upon progression after treatment with TKIs constitutes 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 protein in immunodeficient mice. In particular, CPO301 showed potent anti-tumor efficacy in a human NSCLC PDX model harboring EGFR triple mutations (Exon19Del, T790M and C797S) that are resistant to the third-generation EGFR-TKI Osimertinib. Excellent safety and tolerability have been demonstrated in preclinical toxicology and safety pharmacology studies.

The granting of Fast Track Designation by the FDA recognizes that CPO301 has demonstrated the potential to treat a serious or life-threatening disease and will facilitate the development and expedite the review of CPO301 in the U.S.

A multicenter, first-in-human, dose escalation and dose expansion Phase I clinical trial is underway in the U.S. and Canada, with first patient dosing completed on 6 June 2023, to evaluate the safety, pharmacokinetics and preliminary efficacy of CPO301 in patients with advanced NSCLC.

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

Hong Kong, 12 June 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.