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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

CPO301 GRANTED THE THIRD FAST TRACK DESIGNATION BY U.S. FDA FOR THE TREATMENT OF ADULT PATIENTS WITH NSCLC

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 (also known as SYS6010 in China), a first-in-class epidermal growth factor receptor (“**EGFR**”) antibody drug conjugate (ADC) developed by the Group, has been granted the third Fast Track designation by the U.S. Food and Drug Administration (“**FDA**”) for the treatment of adult patients with advanced or metastatic non-squamous non-small cell lung cancer (Nsq-NSCLC) without EGFR mutations or other actionable genomic alterations (AGA), with prior disease progression on platinum-based chemotherapy and an anti-PD-(L)1 antibody.

Previously, CPO301 received two Fast Track designations from the FDA: the first in June 2023 for the treatment of patients with metastatic non-small cell lung cancer (“**NSCLC**”) harboring EGFR mutations who are relapsed/refractory to or ineligible for EGFR targeting therapy such as a 3rd-generation EGFR inhibitors including Osimertinib; and the second in September 2024 for the treatment of patients with recurrent or metastatic squamous non-small cell lung cancer (Sq-NSCLC) with EGFR overexpression that has progressed on or after treatment with platinum-based chemotherapy and anti-PD-(L)1 therapy.

Lung cancer is the leading cause of cancer incidence and mortality worldwide, with an estimated 2.5 million new cases and 1.8 million deaths globally. Activating EGFR gene mutations and overexpression of EGFR protein are drivers in lung cancer with EGFR mutations as well as in histopathologic subtypes that do not possess EGFR mutations but express elevated levels of wild-type EGFR protein, including both squamous cell carcinoma and adenocarcinoma. The Fast Track designations in all subtypes of NSCLC were granted based on promising clinical efficacy data, showing more promising activity as compared to currently available therapies in NSCLC and other tumor types.

CPO301 is a humanized monoclonal antibody, optimized from cetuximab, and conjugated with a topoisomerase I inhibitor. It is currently undergoing clinical studies simultaneously in China and the U.S. The granting of Fast Track designation by the FDA will facilitate and expedite the development and registration of CPO301 in the U.S. and globally.

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

Hong Kong, 19 May 2025

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. YAO Bing, Mr. CAI Xin and Mr. CHEN Weiping 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.