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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**

## FIRST PATIENT DOSED IN PHASE I CLINICAL TRIAL OF "DOCETAXEL FOR INJECTION (ALBUMIN-BOUND)"

The board of directors (the "**Board**") of CSPC Pharmaceutical Group Limited (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce that "Docetaxel for Injection (albumin-bound)" (the "**Product**") developed by CSPC Zhongqi Pharmaceutical Technology (Shijiazhuang) Co., Ltd.\* (石藥集團中奇製藥技術(石家莊)有限公司), a subsidiary of the Company, has been dosed in the first patient enrolled in the Phase 1 clinical study in the United States. This study is designed to evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of the novel formulation of docetaxel in advanced solid tumors.

The Product employs innovative human albumin encapsulation technology to deliver docetaxel in nanoparticles into patients. With this technology, docetaxel (albumin-bound) will eliminate the need for premedication that is required for all currently marketed docetaxel products, reduce the chance of infusion related hypersensitivity and improve patient compliance. In preclinical studies, docetaxel (albumin-bound) has demonstrated safety in several animal models and enhanced anti-tumor efficacy in several types of solid tumors. Similar albumin encapsulation technology has been demonstrated in paclitaxel products marketed by the Group and other pharmaceutical companies.

The Group is conducting clinical development of the Product concurrently in China and the US. The initial solid tumor indications include gastric and prostate cancers. The Group will endeavor to accelerate both single drug use and combination clinical trials with PD-1 targeting agents.

The Product is a new drug and will be developed via the 505(b)(2) regulatory pathway in the US. Given the extensive use of docetaxel and the advantageous profiles of docetaxel (albumin-bound), the Group will employ innovative trial designs and seek accelerated marketing registration where feasible.

By Order of the Board **CSPC Pharmaceutical Group Limited Cai Dongchen** *Chairman* 

Hong Kong, 30 March 2021

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 and Mr. LAW Cheuk Kin Stephen as independent non-executive directors.