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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

SUBMISSION OF NEW DRUG APPLICATION FOR IRINOTECAN LIPOSOME INJECTION TO 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 the New Drug Application (NDA) for Irinotecan Liposome Injection (the “**Product**”) for the treatment of patients with metastatic pancreatic cancer after disease progression following gemcitabine-based therapy has been submitted to the U.S. Food and Drug Administration (FDA). This is the Group’s first NDA submission for a complex liposome-encapsulated anti-cancer chemotherapy in the U.S.

According to the estimates from the World Health Organization’s International Agency for Research on Cancer (IARC), pancreatic cancer accounted for approximately 495,773 new cases and 466,003 deaths globally in 2020. In Asia, approximately 233,701 new cases and 224,034 deaths were attributed to pancreatic cancer, while in Europe, there were around 140,116 new cases and 132,134 deaths due to this disease. In the U.S., the American Cancer Society estimates that 64,050 new cases of pancreatic cancer will be diagnosed and 50,550 people will die from this disease in 2023. Most pancreatic cancers are diagnosed at late stage, and even those who are diagnosed at early stage and undergo surgery still have high frequency of relapse. The lack of effective treatment options for pancreatic cancer presents significant unmet medical needs.

The NDA submission is based on several discussions with FDA during development, the Pre-NDA meeting, and data from pre-clinical and clinical studies conducted in China. The Product is one of the representative innovative medicines independently developed under the liposome technology platform of the Group. The Product is a sterile, white to slightly yellow opaque isotonic liposomal dispersion, containing 43mg/10mL irinotecan, a topoisomerase 1 inhibitor. Irinotecan is currently used for the treatment of multiple solid tumors such as metastatic pancreatic cancer, colorectal cancer, lung cancer and cervical cancer. It is one component in many combination regimens such as FOLFIRI or FOLFIRINOX for the treatment of these types of cancers.

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

Hong Kong, 18 December 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.