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CSPC

CSPC PHARMACEUTICAL GROUP LIMITED

石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1093)

VOLUNTARY ANNOUNCEMENT

INVESTIGATIONAL NEW DRUG NBL-015 GRANTED ORPHAN-DRUG 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 the antibody drug NBL-015, independently developed by NovaRock Biotherapeutics Limited, a subsidiary of the Company in the United States, was granted orphan-drug designation by the U.S. Food and Drug Administration (FDA) for the treatment of pancreatic cancer.

Pancreatic cancer contributes to the death of more than 430,000 people worldwide per year and is one of the most malignant tumors. According to the statistics of the American Cancer Society in 2019, its one-year general survival rate was 24% and five-year general survival rate was 9% only, being the fourth leading cause of cancer death in the United States. There are very limited choices for diagnosing and treating pancreatic cancer with 90% of the patients diagnosed at the stage of locally advanced or metastatic cancer, and the five-year median survival rate is below 6% after metastasis. Currently the therapies for treating pancreatic cancer are primarily conventional chemotherapy and resection, presenting a highly unmet medical need.

Claudin-18.2 is a highly specific cell-surface molecule widely expressed in gastric and pancreatic tumors. Thus the development of therapeutic antibodies targeting Claudin-18.2 has high anti-cancer potential. NBL-015 is a fully human anti-Claudin-18.2 monoclonal antibody which has been protein engineered to achieve optimized ADCC, CDC and ADCP effects. Preclinical in vitro cell killing studies, animal pancreatic cancer elimination and safety studies have demonstrated that NBL-015 has significant advantages over similar drugs in terms of low immunogenicity, good safety, high affinity and high anti-tumor activity, providing a promising prospect of becoming the best-in-class target therapy for the treatment of pancreatic cancer and gastric cancer.

This orphan-drug designation will allow the Group to communicate with the U.S. FDA frequently and speed up the clinical development, registration and launch of NBL-015. The Group plans to file the clinical trial application for this investigational drug in China and the United States in 2021.

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

Hong Kong, 2 December 2020

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; Mr. LEE Ka Sze, Carmelo as non-executive director; and Mr. CHAN Siu Keung, Leonard, Mr. WANG Bo, Prof. LO Yuk Lam, Dr. YU Jinming and Mr. CHEN Chuan as independent non-executive directors.