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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 FIRST-IN-CLASS PRODUCT SYSA1801
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 SYSA1801, an antibody-drug conjugate (ADC), independently 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, was granted orphan-drug designation by the U.S. Food and Drug Administration (FDA) for the treatment of gastric cancer (including cancer of gastroesophageal junction).

Gastric cancer is a rare disease in the United States, but has a high incidence in Asian countries such as China, Japan and South Korea. Gastric cancer ranks top among various malignant tumors in China, but patients with advanced gastric cancer still have unsatisfactory clinical results in general. In North America, about two-third of gastric cancer patients are diagnosed with locally advanced or metastatic cancer, and local recurrence or distant metastasis occurs in more than half of patients after primary treatment. Besides, the 5-year median survival rate of this cancer is below 10%. Currently there is limited medication or therapy for the treatment of gastric cancer, though conventional chemotherapy and resection are commonly used, presenting an unmet medical need. SYSA1801 is a fully human anti-Claudin-18.2 monoclonal antibody-MMAE drug conjugate. Preclinical in vitro and in vivo animal studies have demonstrated that SYSA1801 can effectively target tumor cells through anti-Claudin-18.2 antibody and trigger endocytosis, bringing MMAE toxins into tumor cells to treat gastric cancer and pancreatic 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 SYSA1801. The Group plans to file the clinical trial application for this investigational drug in China and the U.S. in 2021.

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

Hong Kong, 24 November 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.

* *For identification purpose only*