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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

## 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 antibodydrug 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 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.

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 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.

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

Hong Kong, 7 May 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.