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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**

# RECOMBINANT ANTI-HER2 AND ANTI-CD3 HUMANIZED BISPECIFIC ANTIBODY FOR INJECTION WAS GRANTED CLINICAL TRIAL APPROVAL BY 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 Recombinant Anti-HER2 and Anti-CD3 Humanized Bispecific Antibody for Injection (M802) self-developed by Wuhan YZY Biopharma Co., Ltd.\* (武漢友芝友生物製藥有限公司) ("YZY Biopharma"), a non-wholly owned subsidiary of the Group, was granted clinical trial approval by the U.S. Food and Drug Administration (U.S. FDA).

M802 is developed on the YBODY® bispecific antibody technology platform built by YZY Biopharma. It is the first dual-target specific antibody redirecting T cell and targeting HER2 positive breast cancer and gastric cancer, with effective redirection and stimulation of T cell and having the edge on targeted therapy and immunotherapy.

The M802 project has been granted invention patents in China and the U.S.. It has been granted clinical trial approval by the National Medical Products Administration (NMPA) in 2017 and is now under clinical trial in China. The clinical trial approval in the U.S. will strongly support the commencement of international cooperation and the entry into the international market for innovative drugs by YZY Biopharma.

<sup>\*</sup> for identification purpose only

### About M802 Project:

M802 is a bispecific antibody drug being developed by YZY Biopharma for malignant diseases such as breast cancer and gastric cancer with stable production technology, controllable quality and product quality compliant with the requirements under the Chinese and U.S. pharmacopoeia. In the pre-clinical pharmacology and efficacy study, M802 has been demonstrated to be effective for stimulating T cell, enhancing CD3 positive cell's ability in the identification, integration and cytotoxicity of HER2 positive cell, inhibiting phosphorylation of downstream signaling molecules MAKT & AKT, inhibiting proliferation of HER2 positive tumor cells, and having ADCC & CDC effects.

#### About YZY Biopharma:

YZY Biopharma is a high-tech enterprise focused on the research and development of innovative biopharmaceutical drugs. Since its establishment, it has undertaken the "Major New Drug Development" projects during the national "Twelfth Five-Year Plan" and "Thirteenth Five-Year Plan" periods, the national strategic emerging industry cluster development projects, the national post-doctoral workstations and the establishment of bispecific antibody technology platform in Hubei. Its YBODY® bispecific antibody technology platform is up to leading international standard. The current research and development pipeline covers major disease areas, including oncology, immunology, inflammation, cardiovascular system and infection. Among which, drug candidates HER2×CD3 and EpCAM×CD3 have been granted the first and the second clinical trial approval for self-developed bispecific antibodies for oncology treatment in China respectively and have entered the clinical study stage.

By Order of the Board

CSPC Pharmaceutical Group Limited

Cai Dongchen

Chairman

Hong Kong, 2 September 2019

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. LU Hua, Dr. LI Chunlei, Dr. WANG Qingxi and Mr. CHAK Kin Man 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.