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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**

## CLASS 1 NEW DRUG "PRUSOGLIPTIN TABLETS" MEETS PREDEFINED ENDPOINTS IN THE PIVOTAL CLINICAL TRIALS FOR THE TREATMENT OF TYPE 2 DIABETES

The board of directors (the "**Board**") of CSPC Pharmaceutical Group Limited (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce that class 1 new drug "Prusogliptin Tablets" ("**DBPR108 Tablets**") of 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, has met the predefined endpoints in two pivotal clinical trials for the treatment of type 2 diabetes.

DBPR108 Tablets is a new oral dipeptidyl peptidase-4 (DPP-4) inhibitor which is highly selective and strongly inhibitory towards DPP-4. Through the inhibition of DPP-4, the level of endogenous active glucagon-like peptide-1 (GLP-1) is elevated, which enhances the sensitivity of  $\beta$  cells and  $\alpha$  cells towards glucose, increasing glucose stimulated insulin release while enhancing the inhibitory effect of glucose towards glucagon secretion, thus decreasing blood glucose level.

The Group has initiated two Phase III clinical trials (Phase III monotherapy trial of DBPR108 Tablets and Phase III combination trial of DBPR108 Tablets with metformin) in China as pivotal clinical trials of DBPR108 Tablets for the treatment of type 2 diabetes to support its application for marketing approval. A total of 1,000 subjects with type 2 diabetes were enrolled in the Phase III monotherapy and combination trials, trial results showing favourable clinical effects with predefined endpoints met. Results of the monotherapy trial demonstrated that in respect of the primary efficacy endpoint of the change in HbA1c between the end of 24

weeks and the baseline period, the DBPR108 Tablets group was significantly superior to the placebo group and was non-inferior to the active group of sitagliptin phosphate tablets. Results of the combination trial demonstrated that in respect of the primary efficacy endpoint of the change in HbA1c between the end of 24 weeks and the baseline period, the DBPR108 Tablets group was significantly superior to the placebo group. In addition, safety profile of the DBPR108 Tablets group in the study was similar to the sitagliptin group and placebo group.

Based on the study results, the Group intends to submit an application for pre-NDA communication to the National Medical Products Administration of the People's Republic of China in the near future.

DPP-4 inhibitors (excluding fixed-dose compound) have an expanding market size in China, which exceeded RMB4 billion with a year-on-year growth of nearly 25% in 2021, and promising prospects in the overseas market.

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

Hong Kong, 22 August 2022

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.

\* For identification purposes only