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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

NMPA ACCEPTS MARKETING AUTHORISATION APPLICATION FOR PRUSOGLIPTIN AND METFORMIN EXTENDED-RELEASE TABLETS

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 marketing authorisation application for Prusogliptin and Metformin Extended-Release Tablets (the “**Product**”) developed by the Group has been accepted by the National Medical Products Administration (the “**NMPA**”) of the People’s Republic of China.

The Product is a fixed-dose extended-release combination of the Group’s Class 1 innovative drug, prusogliptin, and metformin hydrochloride, and has been applied for as a Class 2.3 chemical drug under the registration classification of chemical drugs. The proposed indication is: “The Product is used as an adjunct to diet and exercise for adult patients with type 2 diabetes mellitus (“**T2DM**”) who have inadequate glycemic control on metformin monotherapy or who are already receiving combination therapy with prusogliptin and metformin”. Prusogliptin is a dipeptidyl peptidase-4 (“**DPP-4**”) inhibitor that can increase endogenous active GLP-1 levels by inhibiting DPP-4, thereby enhancing glucose-stimulated insulin secretion and strengthening the inhibitory effect of glucose on glucagon secretion, resulting in improved glycemic control. Metformin is a biguanide that reduces hepatic glucose production, inhibits intestinal glucose absorption, and enhances insulin sensitivity by increasing peripheral glucose uptake and utilisation.

In Phase III clinical trials conducted in treatment-naïve T2DM patients and in T2DM patients with inadequate glycemic control on metformin monotherapy, prusogliptin demonstrated favourable efficacy and safety. Compared with metformin monotherapy, the combination of prusogliptin and metformin exhibits significant and sustained glucose-lowering effects with a lower incidence of hypoglycemia and a favourable safety profile. In addition, the Product has a low potential for drug-drug interactions with other medications, and no dose adjustment is required in patients with mild to moderate renal impairment. Compared with coadministration of the two single-agent formulations, the fixed-dose combination can simplify treatment regimens and significantly enhance patient adherence, thereby achieving glycemic control more effectively.

Currently, the Group is also actively advancing the clinical development of a triple drug combination consisting of prusogliptin, dapagliflozin, and metformin hydrochloride, with the aim of benefiting more patients.

By Order of the Board
CSPC Pharmaceutical Group Limited
CAI Dong Chen
Chairman

Hong Kong, 12 January 2026

As at the date of this announcement, the Board comprises Mr. CAI Dong Chen, Dr. CAI Lei, Mr. WEI Qingjie, Mr. ZHANG Cuilong, Mr. WANG Zhenguo, Mr. WANG Huaiyu, Dr. LI Chunlei, Dr. YAO Bing, Mr. CAI Xin, Mr. CHEN Weiping and Mr. QU Zhiyong, as Executive Directors; and Mr. WANG Bo, Mr. CHEN Chuan, Prof. WANG Hongguang, Mr. AU Chun Kwok Alan, Mr. LAW Cheuk Kin Stephen and Ms. LI Quan as Independent Non-executive Directors.