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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 SECOND MARKETING AUTHORISATION APPLICATION FOR EFMEDAGLUTIDE ALFA INJECTION

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 second marketing authorisation application for Edaglutide Alpha Injection (brand name: Shanmeining (善美寧®)) (the "**Product**"), developed by the Company's subsidiary CSPC Baike (Shandong) Biopharmaceutical Co., Ltd., has been accepted by the National Medical Products Administration of the People's Republic of China ("**NMPA**"). The Product is applied for as a Class 1 therapeutic biological product. The indication for this application is glycaemic control in adults with type 2 diabetes. Previously, the marketing authorisation application for the Product for the indication of long-term weight management in overweight or obese adults was accepted by the NMPA in October 2025.

The Product is a recombinant human glucagon-like peptide-1 (hGLP-1) Fc fusion protein injection administered once weekly. The Product can selectively bind to and activate GLP-1 receptors, promoting insulin secretion and inhibiting glucagon release in a glucose concentration-dependent manner, thereby stably reducing blood glucose levels. Concurrently, it can suppress appetite and reduce food intake, providing weight regulation benefits while also improving cardiovascular and metabolic parameters.

This marketing authorisation application is primarily based on two pivotal Phase III clinical studies, which evaluated the efficacy and safety of the Product as a monotherapy and in combination with metformin in Chinese patients with type 2 diabetes, respectively. The results of two pivotal Phase III clinical studies consistently demonstrated that the Product provided comprehensive benefits in lowering glucose levels, reducing weight and improving multiple metabolic parameters. Its onset of action was rapid, with significant clinical effects observed after 4 weeks of dosing, a reduction in HbA1c exceeding 1% from baseline after 8 weeks of dosing, and sustained therapeutic effects maintained for up to 52 weeks. In combination with metformin, the Product exhibited superior long-term glycaemic control outcomes compared with that of dulaglutide. For patients with higher baseline HbA1c levels, the Product can better reduce HbA1c, with a reduction of over 2%. While improving blood glucose levels, the Product can simultaneously improve multiple cardiovascular risk factors such as blood

lipids, blood pressure and body weight, and these benefits continue to increase with the prolongation of treatment time, providing patients with the advantage of integrated metabolic management encompassing glycaemic control, lipid regulation, blood pressure control and weight reduction. Furthermore, the Product demonstrated favourable safety and tolerability profile. Compared with marketed drugs of the same class, the Product showed lower incidence rates of gastrointestinal adverse events and treatment discontinuations due to adverse events. Additionally, its dose escalation regimen is faster and more convenient, requiring only 4 weeks to reach the target maintenance dose.

Based on its advantages in efficacy and safety, the Product possesses significant clinical application value and is expected to become a new treatment option for type 2 diabetes.

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

Hong Kong, 18 June 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, Dr. LI Chunlei, Dr. YAO Bing, Mr. CAI Xin, Mr. CHEN Weiping, Mr. QU Zhiyong and Mr. ZHANG Yiwei 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.*