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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**

#### **OMALIZUMAB FOR INJECTION OBTAINS MARKETING APPROVAL GRANTED BY NMPA**

The board of directors (the “**Board**”) of CSPC Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that Omalizumab for Injection (brand name: Enyitan<sup>®</sup>) (the “**Product**”) developed by the Group has obtained marketing approval granted by the National Medical Products Administration (NMPA) of the People’s Republic of China.

Enyitan<sup>®</sup> is a humanised anti-immunoglobulin E (IgE) recombinant monoclonal antibody and is the first biosimilar drug of Xolair<sup>®</sup> (omalizumab for injection) developed as Class 3.3 therapeutic biological product in China. It is indicated for adults and adolescents (12 years of age and older) with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment. The Product was developed in accordance with the research guidelines for biosimilar drugs and the principle of step-by-step progression. Head-to-head clinical pharmacokinetics and clinical safety and efficacy comparison trials were conducted, on the basis of the comprehensive pharmaceutical and non-clinical comparison studies completed, proving that the Product is highly similar to the originator drug (Xolair<sup>®</sup>) in terms of quality, safety and efficacy, with no clinically meaningful differences. The originator drug has been approved in China for the indications of allergic asthma and chronic spontaneous urticaria in adults and adolescents (12 years of age and older) who remain symptomatic despite H1 antihistamine treatment, with its efficacy and safety being widely recognised.

The approval of the Product will further enrich the Group's product portfolio for autoimmune diseases, and the marketing approval of another indication is also being actively promoted.

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

Hong Kong, 8 October 2024

*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. JIANG Hao, Dr. YAO Bing and Mr. CAI Xin 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.*