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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**

#### **NEW INDICATION FOR ENYITAN<sup>®</sup> (OMALIZUMAB FOR INJECTION) OBTAINS MARKETING APPROVAL**

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 new indication for Omalizumab for Injection (brand name: Enyitan<sup>®</sup>) (the “**Product**”), a Class 3.3 therapeutic biological product developed by CSPC Megalith Biopharmaceutical Co., Ltd., a subsidiary of the Company, for the treatment of moderate to severe persistent allergic asthma has obtained marketing approval granted by the National Medical Products Administration of the People’s Republic of China. It is the second approved indication for Enyitan<sup>®</sup> in China.

Enyitan<sup>®</sup> is a humanised anti-immunoglobulin E (IgE) monoclonal antibody developed by the Group and is a biosimilar drug of Xolair<sup>®</sup>. The Product was developed in accordance with the research guidelines for biosimilar drugs. Through a series of progressive studies, including pharmaceutical, non-clinical and “head-to-head” pharmacokinetic comparisons, and clinical equivalence trials in patients with chronic spontaneous urticaria, it has scientifically, rigorously, comprehensively and systematically confirmed the high similarity between Enyitan<sup>®</sup> and the originator drug (Xolair<sup>®</sup>) in terms of quality, safety and efficacy.

Enyitan<sup>®</sup> is the first omalizumab biosimilar in China approved for marketing under the registration category of Class 3.3 biological product. The previously approved indication is for the treatment of chronic spontaneous urticaria in adults and adolescents (12 years of age and older) who remain symptomatic despite H1 antihistamine treatment.

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

Hong Kong, 10 February 2025

*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. YAO Bing, Mr. CAI Xin and Mr. CHEN Weiping 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.*