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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 ACCEPTANCE OF BIOLOGIC LICENSE APPLICATION OF OMALIZUMAB FOR 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 biologic license application of Omalizumab for Injection (brand name: Kelingda (可令達)) (the “**Product**”) of CSPC Megalith Biopharmaceutical Co., Ltd* (石藥集團巨石生物製藥有限公司), a subsidiary of the Company, has been accepted by the National Medical Products Administration (NMPA) of the People’s Republic of China.

The Product, a humanized monoclonal antibody against human immunoglobulin E (IgE), is a biosimilar to XOLAIR[®]. It is applied as a Class 3.3 therapeutic biological product for the indication of chronic spontaneous urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H₁ antihistamine treatment.

The originator drug has obtained approval 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 recognized.

Through a series of progressive studies in pharmaceutical, non-clinical, clinical pharmacokinetics, and clinical efficacy and safety according to the relevant research guidelines for biosimilars, the Product has been scientifically, rigorously and completely proven to be highly similar to the originator reference drug in terms of quality, safety and efficacy, with no clinically meaningful differences.

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

Hong Kong, 26 June 2023

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, Mr. LAW Cheuk Kin Stephen and Ms. LI Quan as independent non-executive directors.

** For identification purposes only*