CSPC PHARMACEUTICAL GROUP LIMITED
石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1093)

VOLUNTARY ANNOUNCEMENT

MARKETING AUTHORISATION APPLICATION FOR PERTUZUMAB INJECTION ACCEPTED BY THE 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 the marketing authorisation application for Pertuzumab Injection (the "**Product**") developed by 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 (the "**NMPA**") of the People's Republic of China. The Product has been applied for as a Class 3.3 therapeutic biological product. It is indicated for the treatment of HER2-positive breast cancer.

The Product is a recombinant humanised anti-HER2 monoclonal antibody injection administered once every three weeks. It specifically binds to the extracellular dimerisation domain (Subdomain II) of the HER2 receptor and blocks ligand-dependent dimerisation of HER2 with itself or other HER family members, thereby arresting the cell cycle and inducing apoptosis. In addition, the Product is capable of mediating antibody-dependent cell-mediated cytotoxicity.

This application is primarily supported by a Phase III equivalence clinical trial enrolling patients with early-stage or locally advanced HER2-positive breast cancer. Results of clinical trials demonstrated that the Product, when used as neoadjuvant treatment for early-stage or locally advanced HER2-positive breast cancer, is equivalent to the reference drug in terms of efficacy. The Product also exhibited a favourable safety and tolerability profile comparable to those of the reference drug.

The Product was developed in accordance with relevant research guidelines of biosimilars. Through a stepwise program encompassing pharmaceutical studies, non-clinical studies, human pharmacokinetics and clinical efficacy and safety, the Product has been scientifically, rigorously and comprehensively demonstrated to be highly similar to the reference drug in terms of quality, safety and efficacy, with no clinically meaningful differences.

For and on behalf of the Board
CSPC Pharmaceutical Group Limited
CAI Dong Chen
Chairman

Hong Kong, 12 November 2025

As at the date of this announcement, the Board comprises Mr. CAI Dong Chen, Mr. ZHANG Cuilong, Mr. WANG Zhenguo, 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.