CSPC PHARMACEUTICAL GROUP LIMITED
石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1093)

VOLUNTARY ANNOUNCEMENT

SIROLIMUS FOR INJECTION (ALBUMIN-BOUND) WAS GRANTED BREAKTHROUGH THERAPY DESIGNATION IN CHINA

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 Sirolimus for Injection (albumin-bound) (the "**Product**") developed by the Group has been granted Breakthrough Therapy Designation by the National Medical Products Administration (NMPA) of the People's Republic of China for the intended indication of monotherapy for malignant perivascular epithelioid cell tumor (PEComa) (the "**Indication**").

Sirolimus, also known as rapamycin, is a commonly used specific mTOR inhibitor. The oral formulation of sirolimus previously approved for marketing is indicated primarily for the prevention of organ rejection in kidney transplant patients. The Product utilises special technology to encapsulate sirolimus into human serum albumin to overcome the shortcoming that oral formulation fails to deliver sufficient concentration of drug to the target site and has achieved administration of sirolimus by injection without hormone pretreatment. Meanwhile, the Product has expanded the field of application of sirolimus, thus having the potential for treating a series of diseases caused by the mTOR signaling pathway.

Currently, the Product is undergoing multiple phase II and III clinical studies in China for the treatment of solid and hematological tumors, including breast cancer, soft tissue sarcoma, lung cancer, and kidney cancer. Breast cancer ranks first among malignant tumors in women, with approximately 2.3 million new cases of female breast cancer globally, and there is a significant unmet clinical need for patients with HR+/HER2- advanced breast cancer after failure of treatment with CDK4/6 inhibitors. The Product, in combination with endocrine therapy, is the first mTOR inhibitor in China that undergoes clinical trials in patients with HR+/HER2- advanced breast cancer who develop resistance to CDK4/6 inhibitors, and the Group has already submitted an application for communication and exchange of pivotal phase III clinical trials to the regulatory authority.

There is no standard treatment for malignant PEComa in China, representing an unmet clinical need. The Product has now entered the pivotal phase III clinical enrollment stage, with clinical data already confirming that its monotherapy efficacy was significantly better than historical data. The Breakthrough Therapy Designation granted to the Product will further expedite its development progress, making it potentially become the first standard treatment for the Indication in China.

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

Hong Kong, 28 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.