# CSPC PHARMACEUTICAL GROUP LIMITED
# 石藥集團有限公司

*(Incorporated in Hong Kong with limited liability)*

**(Stock Code: 1093)**

## VOLUNTARY ANNOUNCEMENT

## ACCEPTANCE OF APPLICATION FOR MARKETING APPROVAL OF SYHX2011 FOR THE TREATMENT OF ADVANCED BREAST CANCER

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 application for marketing approval of SYHX2011 (the "**Product**") developed by CSPC Ouyi Pharmaceutical Co., Ltd. (石藥集團歐意藥業有限公司), a subsidiary of the Company, has been accepted by the National Medical Products Administration of the People's Republic of China.

Breast cancer is a common malignant tumor among women. Taxanes are the most effective cytotoxic chemotherapy drugs for advanced breast cancer, and have been shown to have greater survival benefits than other types of chemotherapy drugs, whether used alone or in combination therapy. The Product is an innovative nano-formulation developed using patented technology based on Abraxane® (paclitaxel for injection (albumin-bound)), with independent intellectual property rights. The Product was applied as a Class 2.2 chemical drug indicated for the treatment of metastatic breast cancer after failure of combination chemotherapy or breast cancer recurrence within 6 months after adjuvant chemotherapy (prior chemotherapy should have included an anthracycline anticancer drug unless clinically contraindicated).

This application is primarily based on a multicenter, randomised, double-blind pivotal Phase III clinical trial, with the study population consisting of breast cancer patients who are assessed by investigators to be suitable for single-agent antineoplastic therapy with paclitaxel for injection (albumin-bound) in accordance with the China Society of Clinical Oncology (CSCO) Guidelines for Diagnosis and Treatment of Breast Cancer 2022. The clinical trial results demonstrated that the Product had significant therapeutic benefits over paclitaxel for injection (albumin-bound) in patients with advanced breast cancer: the intergroup ratios of the objective response rate assessed by the Independent Review Committee (IRC) and the investigators were 1.38 (95% CI: 1.040, 1.842) and 1.33 (95% CI: 1.020, 1.745) respectively, both meeting the criteria for superiority; the risk of disease progression or death was reduced by 27% (hazard ratio (HR) = 0.73 for progression-free survival (PFS)); and the risk of death was reduced by 33% (HR = 0.67 for overall survival (OS)). In terms of safety, the risk of rash

with the Product decreased by 62%, indicating that the Product was safer in clinical use, which assisted patients in improving their quality of life during treatment and also enhanced patients' adherence to treatment; and, in terms of clinical application, its significantly shortened dispensing time resolved the issues of complex dispensing process and long reconstitution time prior to the use of paclitaxel for injection (albumin-bound), thereby markedly improving the convenience of clinical use.

Leveraging its advantages in efficacy, safety and adherence, the Product is expected to become a new option for the treatment of advanced breast cancer. Concurrently, the Group is also moving forward in clinical trials for other indications of the Product in order to bring benefit to more patients.

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

Hong Kong, 9 December 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. 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.*