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 DRUG APPLICATION FOR SIROLIMUS FOR INJECTION (ALBUMIN-BOUND) 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 new drug application for Sirolimus for Injection (Albumin-Bound) (the "**Product**") independently developed by the Group has been accepted by the National Medical Products Administration (the "**NMPA**") of the People's Republic of China. Following review by the Center for Drug Evaluation of the NMPA, the Product has also been included in the Breakthrough Therapy Drug Program and granted Priority Review status.

The Product is a macrolide antibiotic immunosuppressant and a highly selective inhibitor of the mammalian target of rapamycin ("**mTOR**"). Sirolimus binds to the immunophilin FKBP12 to form an immunosuppressive complex, blocking the activation of the mTOR pathway. On the one hand, it inhibits cytokine-mediated T-lymphocyte activation and proliferation, and arrests cell cycle progression from the G1 phase to the S phase; on the other hand, it downregulates antibody production, thereby exerting potent immunosuppressive effects. The new drug application for the Product was submitted as a Class 2.2 modified new drug under chemical drug classification, with a proposed indication for unresectable locally advanced or metastatic malignant perivascular epithelioid cell tumour ("**PEComa**").

The new drug application is primarily based on a pivotal Phase Ib/III clinical study that enrolled patients with histologically confirmed, unresectable locally advanced or metastatic malignant PEComa who had not previously received mTOR inhibitor therapy. The pivotal Phase III clinical trial met its predefined primary endpoint. Compared with the investigator's choice of conventional therapies in the control group, the Product demonstrated significant efficacy advantages, with statistically significant and clinically meaningful results, enabling rapid and deep tumour responses. Given the current lack of a unified standard treatment regimen for malignant PEComa, the Product has the potential to establish a new treatment standard in this therapeutic area and support the development of a standardised treatment

framework for the benefit of patients with PEComa. The Product has demonstrated a favourable overall safety profile, with generally manageable adverse reactions and a wide safety margin. Its favourable benefit-risk profile makes it a core therapeutic drug for this rare and difficult-to-treat tumour type.

Sirolimus for Injection (Albumin-Bound) is the first intravenous sirolimus formulation approved for clinical research in China. At present, the Group is advancing a pivotal Phase III clinical trial of the Product in combination with fulvestrant for the treatment of HR+/HER2- breast cancer and continues to explore the efficacy and safety of the Product as a monotherapy and in combination regimens across various solid tumours, with the aim of benefiting more cancer patients in the future.

By Order of the Board
CSPC Pharmaceutical Group Limited
CAI Dong Chen
Chairman

Hong Kong, 27 July 2026

As at the date of this announcement, the Board comprises Mr. CAI Dong Chen, Dr. CAI Lei, Mr. WEI Qingjie, Mr. ZHANG Cuilong, Mr. WANG Zhenguo, Dr. LI Chunlei, Dr. YAO Bing, Mr. CAI Xin, Mr. CHEN Weiping, Mr. QU Zhiyong and Mr. ZHANG Yiwei 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.