CSPC PHARMACEUTICAL GROUP LIMITED
石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1093)

VOLUNTARY ANNOUNCEMENT

Phase Ib/III Clinical Study of Sirolimus for Injection (Albumin-Bound) (HB1901) for the Treatment of Advanced Malignant Perivascular Epithelioid Cell Tumour (PEComa) Meets Primary Endpoint

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 Phase Ib/III clinical study (Study Protocol No.: "**HB1901-004**") of Sirolimus for Injection (Albumin-bound) ("**HB1901**"), independently developed by the Company's subsidiary, CSPC Zhongqi Pharmaceutical Technology (Shijiazhuang) Co., Ltd., for the treatment of advanced malignant perivascular epithelioid cell tumour ("**PEComa**") has successfully met its pre-specified primary efficacy endpoint, with the study results demonstrating both statistically significant differences and clear clinical benefits. HB1901 has showed excellent efficacy and is expected to fill the therapeutic gap for this indication in China, potentially becoming the first standard treatment regimen for advanced malignant PEComa in the domestic market.

Malignant PEComa is a relatively rare mesenchymal tumour composed of perivascular epithelioid cells with distinctive histological and immunohistochemical features. These tumours are typically large in size, accompanied by marked nuclear atypia, readily identifiable mitotic figures, tumour necrosis, and infiltrative growth, exhibiting an aggressive clinical course. Approximately 50% of patients with malignant PEComa are already at an advanced stage upon diagnosis, often complicated by metastasis, resulting in a poor prognosis. For patients with advanced malignant PEComa whose tumours cannot be completely resected, or who experience postoperative recurrence and distant metastasis, there is currently no recognised standard treatment regimen in China. Clinical therapeutic options remain scarce, representing a substantial and urgent unmet medical need.

HB1901-004 is a Phase Ib/III clinical study designed to evaluate the safety and efficacy of Sirolimus for Injection (Albumin-bound) in patients with advanced malignant PEComa. Specifically, the pivotal Phase III clinical study, conducted in a head-to-head comparison against the investigator's choice of therapy, comprehensively validated the overall advantages of HB1901 over existing conventional treatments in terms of anti-tumour efficacy, clinical benefit, and safety/tolerability profile. This fully solidifies its clinical application value for rare and refractory tumours, offering a novel and highly effective treatment option for patients with advanced malignant PEComa.

About Sirolimus for Injection (Albumin-bound) (HB1901)

HB1901 is a sirolimus albumin-bound nanoparticle suspension for injection with sirolimus as its active pharmaceutical ingredient (API). It is a modified new drug not yet marketed domestically or overseas. As a preparation that contains a known active ingredient with a new dosage form (including a new drug delivery system) and/or a new route of administration, HB1901 is classified as a Class 2.2 new drug under the registration classification of chemical drugs in accordance with the Measures for the Administration of Drug Registration.

Sirolimus has poor water solubility and is difficult to deliver effectively, which limits its application in the oncology field. HB1901 is an injectable formulation developed by the Group using innovative technology to encapsulate sirolimus in human serum albumin. It is also the first intravenously administered sirolimus formulation to obtain clinical trial approval in China. The Group has therefore successfully achieved the injectable delivery of sirolimus, effectively overcoming the disadvantages of traditional oral formulations, such as low bioavailability and inability to deliver sufficient drug concentrations to target sites, thereby expanding the application of this drug in the oncology field. Compared with marketed tablet and oral suspension formulations of mTOR inhibitors, HB1901 is expected to significantly improve the bioavailability of sirolimus and reduce gastrointestinal toxicity.

In February 2025, HB1901 was granted Breakthrough Therapy Designation by the National Medical Products Administration (NMPA). Currently, multiple clinical trials exploring the efficacy and safety of Sirolimus for Injection (Albumin-bound) in combination with different agents across various tumour types are steadily advancing.

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

Hong Kong, 20 April 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, Mr. WANG Huaiyu, 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.