

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



四环医药
SihuanPharm

Sihuan Pharmaceutical Holdings Group Ltd.

四環醫藥控股集團有限公司

(incorporated in Bermuda with limited liability)

(Stock Code: 0460)

VOLUNTARY ANNOUNCEMENT

NEW INDICATION OF XUANZHU BIOPHARMACEUTICAL'S CLASS 1 INNOVATIVE DRUG BIROCICLIB WAS APPROVED FOR PHASE II CLINICAL TRIAL

The board of directors (the “**Board**”) of Sihuan Pharmaceutical Holdings Group Ltd. (the “**Company**” or “**Sihuan Pharmaceutical**”, together with its subsidiaries, the “**Group**”) is pleased to announce that the Phase II clinical trial application of Birociclib (XZP-3287, CDK4/6 inhibitor), a class 1 innovative drug under development by the Group’s non-wholly owned subsidiary Xuanzhu Biopharmaceutical Co., Ltd. (“**Xuanzhu Biopharmaceutical**”), used as monotherapy or in combination with Abitherone acetate and prednisone in the treatment of metastatic prostate cancer has been approved by the Center for Drug Evaluation of the National Medical Products Administration (the “**NMPA**”) of the People’s Republic of China.

Prostate cancer is one of the common malignant tumors in the genitourinary system of elderly men. Its incidence rate and mortality rate rank second and fifth in the global spectrum of male malignant tumors, and sixth and seventh in Chinese men respectively. According to global market research and consulting firm Nova One Advisor, the global prostate cancer treatment market size is estimated to be \$15.2 billion in 2021 and is expected to increase to \$24.9 billion by 2030.

In 2021, the number of new cases of prostate cancer in China reached 120,000, of which 54% were diagnosed with metastasis at the first visit, and the patient population was relatively large. Pre-clinical studies indicate that the combination of Birociclib and Abitherone acetate has a significant synergistic anti-tumor effect on prostate cancer cells.

About Birociclib

The phase I clinical data demonstrated that Birociclib, a novel selective CDK4/6 inhibitor, has the potential to overcome endocrine therapy resistance in hormone receptor-positive (HR+) breast cancer patients. Birociclib monotherapy also exhibited efficacy in patients with advanced breast cancer who have failed in multiple lines of treatment. Pre-clinical data showed that Birociclib has a unique pharmacokinetic profile, which allows it to go through the blood-brain barrier effectively, and thus it is expected to have potential efficacy in breast cancer patients with brain metastases and brain tumor patients. Moreover, due to the novel targeting mechanism of CDK4/6, Birociclib is able to demonstrate significant clinical benefits and extensive market prospect through multiple novel Birociclib-based combination therapies.

About Xuanzhu Biopharm

Xuanzhu Biopharmaceutical is the innovative drug subsidiary of Sihuan Pharmaceutical. It is an innovative pharmaceutical company with roots in China and a global perspective, focusing on major diseases such as digestion, oncology and non-alcoholic steatohepatitis, and is committed to the continuous research and development, production and commercialization of class 1 drugs with core proprietary intellectual property rights to address unmet clinical medical needs. The company has a team with extensive experience in the development and industrialisation of innovative drugs. Having been involved in the research of digestion, oncology and non-alcoholic steatohepatitis for many years, the company has a deep understanding and international vision of the development of new drugs in related fields and their future development direction. The company has two R&D platforms: small molecule chemistry and large molecule biologics. The dual engines drive the company's innovation and development, forming a product pipeline that covers small molecule, monoclonal antibodies, bispecific antibodies, antibody-drug conjugate (ADC) and other types of products. The company adheres to the strategic concept of "innovation driven, promoting the development of new drugs in China and serving human health", and the values of "open innovation, courageous commitment, overcoming difficulties and scientific rigor". With a focus on unmet clinical needs, the company continues to develop new class 1 drugs with international competitiveness, and is committed to developing into a first-class innovative pharmaceutical company with independent research and development, production, and sales capabilities.

About Sihuan Pharmaceutical

Founded in 2001 and listed on the Main Board of The Stock Exchange of Hong Kong Limited in 2010, Sihuan Pharmaceutical is an international medical aesthetic and biopharmaceutical company led and driven by innovation, with an independent and leading research and development technology platform, a rich global product pipeline, strong product registration capability, a full dosage form production platform with high efficiency and low cost and a mature and excellent sales system. Adhering to the overall strategic objective of "full promotion of a two-wheel drive strategy of its medical aesthetics and biopharmaceutical businesses", Sihuan Pharmaceutical endeavours to build itself into a leading medical aesthetics and biopharmaceutical company in China.

This announcement is being made by the Company on a voluntary basis to update the investing public on the Group's latest business development, and does not constitute, and is not intended to be, an advertisement regarding the use of any medicine, surgical appliance, treatment or orally consumed product.

By order of the Board
Sihuan Pharmaceutical Holdings Group Ltd.
Dr. Che Fengsheng
Chairman and Executive Director

Hong Kong, 3 July 2023

As at the date of this announcement, the executive directors of the Company are Dr. Che Fengsheng (Chairman), Dr. Guo Weicheng (Deputy Chairman and Chief Executive Officer), Dr. Zhang Jionglong, Ms. Chen Yanling and Ms. Miao Guili; and the independent non-executive directors of the Company are Mr. Tsang Wah Kwong, Dr. Zhu Xun and Mr. Wang Guan.