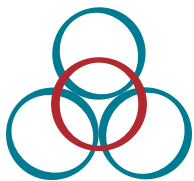


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四环医药
SihuanPharm

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

THE NDA OF CLASS 1 INNOVATIVE DRUG BIROCICLIB'S MONOTHERAPY, INDEPENDENTLY DEVELOPED BY XUANZHU BIOPHARM FOR THE TREATMENT OF ADVANCED BREAST CANCER, WAS ACCEPTED BY NMPA

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 new drug application (“**NDA**”) of Birociclib (XZP-3287, CDK4/6 inhibitor) (“**Birociclib**”), a class 1 innovative drug independently developed by the Group’s non-wholly owned subsidiary Xuanzhu Biopharmaceutical Co., Ltd. (“**Xuanzhu Biopharm**”), has been accepted by the National Medical Products Administration (the “**NMPA**”) of the People’s Republic of China (“**China**”). Specifically, Birociclib is used as a single agent for the treatment of locally advanced or metastatic adult breast cancer patients with hormone receptor (HR) positive and human epidermal growth factor receptor 2 (Her2) negative who have received two or more endocrine treatments and one chemotherapy treatment in the past metastatic stage and have disease progression.

Birociclib is the only CDK4/6 inhibitor in China that has conducted clinical research to verify the clinical efficacy of a single agent. For HR+/Her2- patients with locally advanced or metastatic breast cancer who have received two or more endocrine treatments and one or more chemotherapy in the metastatic stage and have disease progression, the ORR of Birociclib monotherapy assessed by the Independent Review Committee (IRC) was 30.0%, the median DoR was 14.78 months, the median PFS was 9.17 months, and the median OS was 29.01 months. Compared with mono-chemotherapy and novel antibody-drug conjugate (“**ADC**”) drug therapy (ORR: 8.1%~21%; median PFS: 2.6~5.5 months; median OS: 8.0~17.8 months), it shows better treatment response rate, longer remission duration, progression free survival, and better overall survival, with better long-lasting treatment benefits. In addition, compared to intravenous chemotherapy drugs, Birociclib, as an oral drug, is safer, more convenient and more accessible for patients with advanced tumors.

About Birociclib

Birociclib is an oral small molecule CDK4/6 inhibitor independently developed by Xuanzhu Biopharm. Based on innovative technology and design, Birociclib has good enzymatic inhibitory activity against CDK4 and CDK6, higher selectivity for CDK4, and good inhibitory effect on CDK2. In clinical research, Birociclib has shown significant anti-tumor effect. Both monotherapy and combinational therapy with endocrine have shown good effectiveness in patients with HR positive and Her2 negative advanced breast cancer, exhibiting good safety and tolerance, which can achieve continuous dosing. At present, the NDA application of Birociclib's monotherapy and combinational therapy with fulvestrant in the treatment of advanced breast cancer have both been accepted by NMPA.

About Xuanzhu Biopharm

Xuanzhu Biopharm 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, 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 Group 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, 17 October 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.