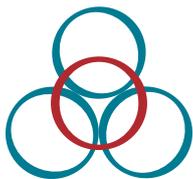


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四环医药
SihuanPharm

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 TABLETS, INDEPENDENTLY DEVELOPED BY XUANZHU BIOPHARMACEUTICAL, 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 tablets (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 in combination with fulvestrant is used for the treatment of breast cancer patients who have hormone receptor-positive(HR+) and human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer that has progressed on previous endocrine therapy. Birociclib is the first anti-tumor innovative drug applied for marketing by Xuanzhu Biopharm.

Birociclib, as a CDK4/6 inhibitor self-developed in China, has unique molecular structure design and favorable advantages of being effective as a single agent, being able to administer continuously and being able to cross the blood-brain barrier. The phase III clinical research results indicate that Birociclib in combination with fulvestrant has significant statistical differences and clinical benefits comparing to the control group.

According to the data from the International Agency for Research on Cancer (IARC) of the World Health Organization, breast cancer is the most prevalent malignant tumor in women worldwide, and hormone receptor-positive (HR+) and human epidermal growth factor receptor 2-negative (HER2-) breast cancer has the highest proportion among all breast cancer types for approximately 65%-70%. At present, the most popular drug in this field is CDK4/6 inhibitor, which restore cell cycle control and block tumor cell proliferation by selectively inhibit CDK4/6. In 2022, the global sales of CDK4/6 inhibitor exceeded US\$8 billion, and exceeded RMB 1 billion in China. The global market size is expected to exceed US\$15 billion by 2025, a large market for this type of drug.

About Birociclib

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 distinctive pharmacokinetic profile, which allows it to go through the blood-brain barrier, and thus it is expected to have potential efficacy for brain metastases in breast cancer patients and in patients with brain tumor. Moreover, due to the novel targeting mechanism of CDK4/6, Birociclib is amenable in combination with other therapies for additional clinical applications and thus potentially a broader market perspective.

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, 5 September 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.