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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 APPLICATION FOR THE NDA OF XUANZHU BIOPHARM'S INDEPENDENTLY DEVELOPED CLASS 1 INNOVATIVE DRUG “DEXITINIB TABLETS” TO THE NMPA WAS ACCEPTED

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 “Dexitinib tablets” (Product code: XZP-3621), which is an anti-tumor class 1 innovative drug independently developed by Xuanzhu Biopharmaceutical Co., Ltd. (“**Xuanzhu Biopharm**”), a non-wholly owned subsidiary of the Company, submitted New Drug Application (“**NDA**”) to the National Medical Products Administration (the “**NMPA**”) of China and was accepted. The specific indication for this application is for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, locally advanced or metastatic non-small-cell lung cancer (NSCLC). **Dexitinib tablets is the first targeted innovative drug for lung cancer that Xuanzhu Biopharm has submitted NDA for and received acceptance. If the application for the NDA of the product is approved, it will be the third innovative drug independently developed by Xuanzhu Biopharm to be approved for launch.**

Dexitinib tablets (Product code: XZP-3621) is a new generation of ALK inhibitor drug, the unique structural design of which enhances the molecule’s inhibitory activity against drug-resistant mutations. The clinical research results indicate that XZP-3621 shows excellent activity against first generation and some second-generation ALK inhibitor resistance mutations for advanced NSCLC; compared to the same category drugs that have been launched, XZP-3621 demonstrates higher objective response rate (ORR) and better safety profile in the treatment of ALK positive locally advanced or metastatic NSCLC patients. In addition, XZP-3621 can cross the blood-brain barrier and is effective for tumor brain metastasis.

According to the latest cancer report released by the International Agency for Research on Cancer (IARC), in 2022, lung cancer emerged as the top malignancy in terms of both incidence rate and mortality globally and in China. Among them, about 80% are NSCLC, and ALK rearrangements are detected in about 3–7% of NSCLC. According to CIC (China Insights Consultancy) data, the market scale of targeted drugs for ALK-fusion advanced NSCLC in China is expected to increase from about RMB3.37 billion in 2021 to about RMB6.96 billion in 2030. Due to the frequent emergence of drug resistance to ALK inhibitors, uses of the first to third generation ALK inhibitor drugs will be changed based on the resistance patterns in clinical practice. In addition, ALK positive advanced NSCLC patients have a longer overall survival period (according to public information, the 5-year survival rate of ALK positive advanced NSCLC patients exceeds 60%), so the safety of ALK inhibitors is extremely important. XZP-3621 is effective against multiple resistance mutations associated with the first-generation and some second-generation drugs; and the side effects are much lower than the competitive drugs of the same category. With excellent safety profile, it will be gladly accepted by doctors and patients, the commercial value and clinical value are both high in the future.

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, 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 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, 2 May 2024

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.