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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

Successful Enrollment of First Patient for the Clinical Trial of Innovative Patented Oncology Drug — Pirotinib in the United States

The board of directors (the "**Board**") of Sihuan Pharmaceutical Holdings Group Ltd. (the "**Company**" or "**Sihuan Pharmaceutical**" together with its subsidiaries, the "**Group**") announces that the Phase I clinical trial of Pirotinib ("**Pirotinib**" or the "**new drug**"), the first innovative patented oncology drug successfully developed by Shandong XuanZhu Pharma Co., Ltd. ("**Shandong XuanZhu**"), a wholly-owned subsidiary of the Group, has successfully enrolled the first patient in the United States ("**U.S.**"). The Patient was administered with the first dose for Phase I clinical trial on 8 April 2015 (U.S. Time), which marked the milestone of the Group's innovative drugs global development.

Pirotinib, a novel irreversible pan-epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) for the treatment of lung cancer, gastric cancer as well as other malignancies with unmet medical needs. Preclinical trail *in vitro* and *in vivo* studies demonstrate that Pirotinib has excellent antitumor efficacy, distinct pharmacokinetics profiles and tissue distribution, and excellent safety profiles. The Investigational New Drug (IND) application for Pirotinib was submitted to the U.S. Food and Drug Administration ("**U.S. FDA**") on 27 October 2014 (U.S. Time), and the clinical trial approval was granted by U.S. FDA on 26 November 2014 (U.S. Time).

After the clinical trial approval was granted by the U.S. FDA, Shandong XuanZhu has been working closely with Covance Inc. ("**Covance**"), one of the world's largest contract research organization (CRO), for the preparation and initiation of clinical trial in the U.S..

The Phase I clinical trial of Pirotinib, which consists of an initial dose escalation phase and a following dose expansion phase, is conducted on patients with advanced solid tumors. The primary objective of this study is to determine the maximum tolerated dose (MTD) or recommended Phase II dose (RP2D) and assess dose-limiting toxicity (DLT) of Pirotinib as a single agent when administered orally to patients. Additionally, the safety and tolerability, pharmacokinetic profile, and preliminary antitumor activity of Pirotinib will be evaluated during this clinical trial. During the dose expansion phase, non-small cell lung cancer, gastric cancer, and colorectal cancer patients harboring certain types of oncogenic mutations in the EGFR family will be enrolled for clinical trial in order to evaluate the pharmacodynamic effects of Pirotinib.

The Phase I clinical trial of Pirotinib will be conducted in three well-known cancer research centers in the U.S., namely, the University of Texas MD Anderson Cancer Center ("**MDACC**"), the Indiana University Melvin and Bren Simon Cancer Center and the Huntsman Cancer Institute ("**HCI**") of the University of Utah. The first patient enrolled is from MDACC.

The official initiation of Phase I clinical trial of Pirotinib in the U.S. and the cooperation with Covance and other international research and development institutions showcase that the Group has made a solid step forward in the international development of the Group's new drugs.

This announcement is being made by the Company on a voluntary basis to let the investing public understand 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.
Che Fengsheng
Chairman and Executive Director

Hong Kong, 9 April, 2015

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) and Mr. Meng Xianhui; the non-executive directors of the Company are Dr. Zhang Jionglong and Mr. Homer Sun; and the independent non-executive directors of the Company are Mr. Patrick Sun, Mr. Tsang Wah Kwong and Mr. Zhu Xun.