Simcere Pharmaceutical Group Limited
先聲藥業集團有限公司
(Incorporated in Hong Kong with limited liability)
(Stock code: 2096)

VOLUNTARY ANNOUNCEMENT

CONDITIONAL APPROVAL FOR MARKETING IN CHINA OF ANTI-SARS-COV-2 INNOVATIVE DRUG XIANNUOXIN™ (SIMNOTRELVIR TABLETS/RITONAVIR TABLETS (CO-PACKAGED)) GRANTED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

This announcement is made by Simcere Pharmaceutical Group Limited (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to inform shareholders and potential investors of the Company about the latest business development of the Group.

The board (the "**Board**") of directors ("**Directors**", and each a "**Director**") of the Company is pleased to announce that on January 28, 2023, the innovative drug XIANNUOXIN™ (先諾欣®) (Simnotrelvir Tablets/Ritonavir Tablets (co-packaged)), which was jointly developed by the Group with Shanghai Institute of Materia Medica (the "**SIMM**") and Wuhan Institute of Virology (the "**WIV**"), Chinese Academy of Sciences (the "**CAS**"), has been conditionally approved for marketing in China by the National Medical Products Administration of China (NMPA) with urgent review and approval under Special Examination and Approval of Drugs (藥品特別審批程序) (Approval No. H20230001). XIANNUOXIN™ will be used for the treatment of adult patients infected with mild to moderate COVID-19 and its recommended dosage is 0.750g of Simnotrelvir (0.375g×2 tablets) in combination with 0.1g of Ritonavir (0.1g×1 tablet) orally for every 12 hours for 5 consecutive days.

A multi-centered, randomized, double-blind, placebo-controlled phase II/III clinical study in China (the "**Study**") to evaluate the efficacy and safety of XIANNUOXIN™ met the pre-specified primary efficacy endpoint. The study randomized 1,208 adult patients with symptomatic mild to moderate COVID-19. The results showed that XIANNUOXIN™ was effective in accelerating recovery from symptoms and shortening the duration of disease compared to placebo: a significant reduction of the time to first occurrence of sustained recovery of 11 target COVID-19 symptoms by approximately 1.5 days, with a significant reduction of approximately 2.4 days for the subgroup population with at least one high risk factor for progression to severe COVID-19, while the data suggest superior efficacy of XIANNUOXIN™ with early use. XIANNUOXIN™ also demonstrates significant antiviral effects: viral load reduced rapidly and significantly after dosing; viral load reduced up to over 96%(treatment difference in change from baseline 1.43 $\log_{10}$ copies/mL) compared to placebo on day 5 after dosing; and nucleic acid conversion time shortened by approximately 2.2 days. Safety data show that XIANNUOXIN™ is safe and well tolerated for Chinese patients infected with mild to moderate COVID-19. Detailed data of the Study are expected to be released in academic journals or conferences in the future.

The results of the Study demonstrated that XIANNUOXIN™ is safe and effective to adult patients infected with mild-moderate COVID-19 and is of extensive clinical values. As the first 3CL target anti-SARS-CoV-2 innovative drug with independent intellectual property rights in China, the successful marketing of XIANNUOXIN™ is expected to bring patients in China with a more effective treatment option.

ABOUT THE STUDY

The subjects included in the Study are with symptomatic mild to moderate COVID-19, who are ≥ 18 years old, the first infection of SARS-CoV-2 ≤ 5 days, and the onset of COVID-19 symptoms ≤ 3 days. The primary endpoint of the Study is the time from the first dosing to the first occurrence of sustained recovery of 11 target COVID-19 symptoms. The sustained recovery is defined that the scores of all 11 target COVID-19 symptoms of subjects are 0 for two successive days. The secondary endpoints include virological indicators, etc. 11 target COVID-19 symptoms include cough, nasal congestion and runny nose, sore or dry throat, shortness of breath or difficulty breathing, headache, feeling feverish or fever, chills or shiver (or shivering), etc.

On August 19, 2022, the first patient was enrolled in the Study, and the enrollment of all 1,208 patients was accomplished on December 16, 2022. The Study has established a total of 43 clinical research centers in 20 provinces, municipalities and autonomous regions in China.

The Study is so far the first phase III registrational clinical study for Chinese patient population infected with the SARS-CoV-2 Omicron variants that has completed the planned number of patient enrollment. The Study was designed in accordance with international guidance, and was the first phase III registrational clinical study worldwide which has met the primary endpoint as time to sustained recovery of 11 symptoms.

ABOUT XIANNUOXIN™

XIANNUOXIN™ (Simnotrelvir Tablets/Ritonavir Tablets (co-packaged)) is an oral small molecule anti-SARS-CoV-2 innovative drug. Simnotrelvir targets 3CL protease which is essential for SARS-CoV-2 virus replication, and its combination with low-dose Ritonavir helps to slow down the metabolism or breakdown of Simnotrelvir in body in order to improve the antiviral effect. Preclinical animal research indicated that XIANNUOXIN™ showed potent, broad-spectrum anti-SARS-CoV-2 activity with no genotoxicity observed. On November 17, 2021, the Group entered into a technology transfer contract with the SIMM and the WIV of the CAS, pursuant to which the Group obtained the development, production and commercialization rights on an exclusive basis of Simnotrelvir (SIM0417) worldwide.

ABOUT SIMM

Founded in 1932, SIMM, CAS is the oldest comprehensive innovative drug research institute in China. In line with frontiers in life sciences and aiming at solving key scientific problems in drug discovery, SIMM carries out research on innovative drug basis and application basis, developing new theories, methods and technologies and focuses on the new drug R&D.

ABOUT WIV

Founded in 1956, WIV, CAS is the comprehensive research institution specializing in basic research on virology and related technological innovation. Regarding the significant demands in the areas of national population health and biosafety, WIV focuses on the basic and applied basic research in virology, immunology, emerging biotechnology, etc.

ABOUT THE COMPANY

The Company is an innovation and R&D-driven pharmaceutical company. It has established a State Key Laboratory of Translational Medicine and Innovative Drug Development. The Company focuses on the therapeutic areas of oncology, central nervous system, autoimmunity and anti-infection, with forward-looking layout of disease areas that may have significant clinical needs in the future, aiming to achieve the mission of "providing today's patients with medicines of the future". Driven by its in-house R&D efforts and synergistic innovation, the Company has established strategic cooperation partnerships with many innovative companies and research institutes.

By order of the Board
Simcere Pharmaceutical Group Limited
Mr. Ren Jinsheng
Chairman and Chief Executive Officer

Hong Kong, January 29, 2023

As at the date of this announcement, the Board comprises Mr. REN Jinsheng as the Chairman and executive Director, Mr. TANG Renhong, Mr. WAN Yushan and Ms. WANG Xi as the executive Directors; and Mr. SONG Ruilin, Mr. WANG Jianguo, Mr. WANG Xinhua and Mr. SUNG Ka Woon as the independent non-executive Directors.