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Sincere 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

NEW DRUG APPLICATION OF ANTI-SARS-COV-2 INNOVATIVE DRUG XIANNUOXIN™ (SIMNOTRELVIR TABLETS/ RITONAVIR TABLETS (CO-PACKAGED)) ACCEPTED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

This announcement is made by Sincere 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 16, 2023, the New Drug Application (“**NDA**”) of 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 accepted by the National Medical Products Administration of China (“**NMPA**”) under Special Examination and Approval of Drugs (藥品特別審批程序). XIANNUOXIN™ is intended to be used for the treatment of adults infected with mild to moderate COVID-19.

ABOUT XIANNUOXIN™

XIANNUOXIN™ (Simnotrelvir Tablets/Ritonavir Tablets (co-packaged)) is an oral small molecule anti-SARS-CoV-2 drug. Simnotrelvir targets 3CL protease which is essential for SARS-CoV-2 viral replication, and co-administration with a low dose of ritonavir helps to slow the metabolism or breakdown of simnotrelvir in vivo in order to improve the effect of combating the virus. In pre-clinical animal trials, XIANNUOXIN™ has demonstrated highly potent and broad-spectrum antiviral activity, and no genetic toxicity was found. 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 development, production and commercialization rights on an exclusive basis of simnotrelvir (SIM0417) worldwide. On March 28 and May 13, 2022, XIANNUOXIN™ obtained two Clinical Trial Approvals issued by the NMPA for the treatment of patients with mild to moderate COVID-19, etc.

On August 19, 2022, the first patient was enrolled in a multi-center, randomized, double-blind, placebo-controlled phase II/III clinical study (the “**Study**”) to evaluate the efficacy and safety of XIANNUOXIN™ in symptomatic adult patients with mild to moderate COVID-19, and the enrollment of 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 pivotal clinical study for Chinese patient population infected with the SARS-CoV-2 Omicron variants that has completed patient enrollment. The Study was designed in accordance with international guidance, and was the first study worldwide which has met the primary endpoint as “time to sustained recovery (to 0 point) of 11 target symptoms, including cough, nasal congestion and runny nose, sore throat, fever, headache, muscle or body aches, etc.” Detailed data on the efficacy and safety of the Study will be released or published upon XIANNUOXIN™ is approved for marketing.

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 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 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
Sincere Pharmaceutical Group Limited
Mr. Ren Jinsheng
Chairman and Chief Executive Officer

Hong Kong, January 16, 2023

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