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
PUBLICATION BY THE NEW ENGLAND JOURNAL OF MEDICINE ABOUT THE PHASE II/III CLINICAL STUDIES RESULTS OF XIANNUOXIN®, AN ANTI-SARS-COV-2 INNOVATIVE DRUG, FOR THE TREATMENT OF ADULT PATIENTS WITH MILD-TO-MODERATE COVID-19

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 (the "**Directors**") of the Company is pleased to announce that, on January 18, 2024, the New England Journal of Medicine (NEJM, 2022 Impact Factor: 158.5), digitally published the complete data of the Group's phase II/III, double-blind, randomized, placebo-controlled clinical trial (NCT05506176) (the "**Study**") of XIANNUOXIN® (Simnotrelvir Tablets/Ritonavir Tablets (co-packaged)), a 3CL oral innovative drug used for the treatment of adult patients with mild-to-moderate COVID-19 (DOI: 10.1056/NEJMoa2301425).

From August 19, 2022 to December 16, 2022, a total of 1,208 patients were enrolled at 35 research sites in China, with 603 patients in the XIANNUOXIN® group (received 750mg of Simnotrelvir plus 100mg of Ritonavir, twice daily for 5 days) and 605 patients in the placebo group. The results showed that, for adult patients with mild to moderate COVID-19 in China, XIANNUOXIN® could accelerate recovery from symptoms, and shorten the duration of the disease cause, reduce viral load rapidly and significantly, and demonstrate good safety and tolerance:

1. **Significantly shortened the median time to sustained resolution of 11 targeted COVID-19 symptoms (the "Duration"), with greater effectiveness in patients with high risk factors:** In the modified intention-to-treat 1 (the "**mITT1**") population who received the first dose within 72 hours after COVID-19 symptom onset, XIANNUOXIN® could significantly shorten the Duration by 35.8 hours; In the subgroup of patients with risk factors for severe COVID-19, XIANNUOXIN® could shorten the Duration by 60.4 hours.

2. **Demonstration of rapid and significant decrease in viral load:** in the mITT1 population, the additional change in viral load from baseline in the XIANNUOXIN® group was 96.9% (-1.51 $\log_{10}$ copies/mL) compared with placebo group on day 5.

3. **Good safety profile:** the safety data showed the XIANNUOXIN® group reported a slightly higher occurrences of adverse events than placebo group, most of these events were of mild or moderate severity and could be recovered without any medical intervention, which suggesting that XIANNUOXIN® was safe and tolerable.

The median age of the patients included in the Study was 35 years, and 1,092 patients (95.9%) had completed primary vaccination, with 874 patients (76.7%) had received a booster dose. Meanwhile, various Omicron variants were covered in the Study, which demonstrated the application value of XIANNUOXIN® in clinical practice.

The publication of the Study with great success signifies that XIANNUOXIN® has become the first domestically-made 3CL target anti-SARS-CoV-2 drug with a complete evidence chain. Before that, the results of the pre-clinical study, the phase I clinical trial and the phase Ib clinical trial of XIANNUOXIN® have been successively published in prestigious academic journals, such as the sub-journals of Lancet and Nature, during the period from July 2023 to October 2023.

1. On October 13, 2023, the discovery process and the pre-clinical study results of Simnotrelvir, the active ingredient of XIANNUOXIN®, were digitally published on *Nature Communications* (DOI:10.1038/s41467-023-42102-y).

2. On September 30, 2023, the investigation of the phase I clinical study (NCT05339646) results of Simnotrelvir on healthy adults participating into the trial in terms of drug safety, tolerability and pharmacokinetics were digitally published on *European Journal of Pharmaceutical Sciences* (DOI: 10.1016/j.ejps.2023.106598).

3. On July 11, 2023, the assessment of the phase Ib clinical study (NCT05369676) results of Simnotrelvir-Ritonavir for the treatment of COVID-19 in terms of effectiveness and safety were digitally published on *The Lancet Regional Health – Western Pacific* (DOI: 10.1016/j.lanwpc.2023.100835).

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 and clearance of Simnotrelvir in body in order to improve the antiviral effect. On November 17, 2021, the Group entered into a technology transfer contract with Shanghai Institute of Materia Medica and Wuhan Institute of Virology, Chinese Academy of Sciences, pursuant to which, the Group obtained the development, production and commercialization rights on an exclusive basis of Simnotrelvir worldwide.

ABOUT THE COMPANY

The Company is an innovation and R&D-driven pharmaceutical company and has established a "State Key Laboratory of Neurology and Oncology Drug Development". The Company focuses on the therapeutic areas of oncology, nervous system, autoimmune 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 18, 2024

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; Mr. SONG Ruilin, Mr. WANG Jianguo, Mr. WANG Xinhua and Mr. SUNG Ka Woon as the independent non-executive Directors.