**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

# THE CLINICAL TRIAL APPROVAL FOR SIM0501 TABLETS (AN USP1 SMALL-MOLECULE INHIBITOR) ISSUED 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 (the "**Directors**") of the Company is pleased to announce that, on January 10, 2024, SIM0501 tablets, a small-molecule inhibitor of Ubiquitin Specific Peptidase 1 ("**USP1**"), which is an anti-tumor drug candidate independently developed by the Group, has obtained the Clinical Trial Approval issued by the National Medical Products Administration (國家藥品監督管理局) of China, pursuant to which, SIM0501 tablets have been approved to initiate clinical trials for advanced malignant solid tumors as monotherapy.

## ABOUT SIM0501

SIM0501 is an oral, non-covalent and highly selective inhibitor of USP1. USP1 is found to be overexpressed in various tumors and plays a key role in DNA damage response and repair. The inhibition of USP1 can promote apoptosis in tumors, especially in the tumors with homologous recombination deficiency ("**HRD**"). Following the success of PARP inhibitor ("**PARPi**"), the USP1 inhibitor is expected to provide innovative solutions for more patients with solid tumors in the field of "synthetic lethality". In preclinical *in vitro* and *in vivo*

pharmacology studies, SIM0501 has shown significant anti-proliferation activity against HRD tumors as a monotherapy or in combination with PARPi, which demonstrates high potential for clinical development.

On December 2, 2023, the Investigational New Drug (IND) application of SIM0501 to initiate clinical trials for advanced solid tumors was approved by the U.S. Food and Drug Administration (FDA).

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