**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 NEW INDICATION OF SANBEXIN® SUBLINGUAL TABLETS 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 November 28, 2023, a new indication of the Sanbexin® sublingual tablets (Edaravone and Dexborneol sublingual tablets), which was jointly developed by the Group and Neurodawn Pharmaceutical Co., Ltd. (南京寧丹新藥技術有限公司) ("**Neurodawn**"), has obtained the Clinical Trial Approval issued by the National Medical Products Administration (國家藥品監督管理局) (the "**NMPA**") of China, which is intended to be used in the clinical trials of Sanbexin® sublingual tablets for the prophylactic treatment of Post Stroke Cognitive Impairment (PSCI) in patients with Acute Ischemic Stroke ("**AIS**").

## ABOUT SANBEXIN® SUBLINGUAL TABLETS

Sanbexin® sublingual tablets, which contain edaravone and dexborneol as two active ingredients, can disintegrate quickly under the tongue and can be absorbed into the blood through the sublingual venous plexus. Its key pharmacologic activities include anti-inflammations and free radicals scavenging, thus minimizing brain cell injury or impairment caused by AIS. Such unique sublingual formulation is expected to increase the flexibility of stroke treatment and improve medication compliance. Sequential therapy

consisting of the marketed Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection) and Sanbexin® sublingual tablets of the Company is expected to enable patients to receive a complete course of treatment in and outside of the hospital.

On June 28, 2023, the New Drug Application (NDA) of the Sanbexin® sublingual tablets was accepted by NMPA. The first indication is for the improvement of the neurological symptoms, activities of the daily living and dysfunction caused by AIS.

**ABOUT NEURODAWN**

Neurodawn is an innovative company focusing on the development and industrialization of new drugs in the field of central nervous system diseases, and has been named as a Nanjing Cultivated Unicorn Enterprise. The company's project pipeline mainly involves stroke, glioma, cognitive disorders, affective disorders, neuropathic pain, cerebral small vessel disease and other related diseases, which are currently in the clinical and pre-clinical stages respectively.

**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, November 30, 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; Mr. SONG Ruilin, Mr. WANG Jianguo, Mr. WANG Xinhua and Mr. SUNG Ka Woon as the independent non-executive Directors.*