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 JAMA NEUROLOGY ABOUT THE PHASE III CLINICAL STUDIES RESULTS OF SANBEXIN® SUBLINGUAL TABLETS FOR THE TREATMENT OF ACUTE ISCHEMIC STROKE

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 February 19, 2024, the Journal of American Medical Association•Neurology ("**JAMA NEUROLOGY**", IF: 29.0) published online the key results of the multi-center, randomized, double-blind and placebo-controlled phase III clinical study (NCT04950920) (the "**TASTE-SL Study**") of Sanbexin® sublingual tablets (Edaravone and Dexborneol sublingual tablets) used for the treatment of acute ischemic stroke (the "**AIS**") (DOI:10.1001/jamaneurol.2023.5716).

From June 28, 2021 to August 10, 2022, a total of 914 AIS patients within 48 hours of onset were enrolled at 33 research sites in China for the TASTE-SL Study. Among which, 450 patients in the Sanbexin® sublingual tablets group received 36mg dose of sublingual edaravone dexborneol (edaravone 30mg, dexborneol 6mg) twice a day for 14 consecutive days); while 464 patients in the placebo group received sublingual placebo (edaravone 0mg, dexborneol 60μg) twice a day for 14 consecutive days.

The results showed that, compared with placebo, Sanbexin® sublingual tablets have significantly improved the recovery of neurological function and ability to live independently in AIS patients after treatment. The Sanbexin® sublingual tablets group showed a significantly higher proportion of patients experiencing good functional outcomes (mRS score 0~1) on day 90 after randomization, compared with the placebo group (64.4% *vs.* 54.7%; OR=1.50; 95% CI 1.15~1.95; *P*=0.003). For the subgroups in different ages (≤65 or ＞65), genders, times from onset to treatment (≤24h or ＞24h), history of hypertension, history of hyperlipemia, history of diabetes, history of heart disease, and renal functions, the benefits of Sanbexin® sublingual tablets group in improving neurological function are consistent. Sanbexin® sublingual tablets have shown good safety profile in AIS patients, with similar rates of adverse events (AE) within 90 days and treatment related adverse events between the two groups.

ABOUT SANBEXIN® SUBLINGUAL TABLETS

Sanbexin® sublingual tablets is an innovative drug jointly developed by the Group and Neurodawn Pharmaceutical Co., Ltd. (南京寧丹新藥技術有限公司) ("**Neurodawn**"). It contains edaravone and dexborneol as two active ingredients, which can disintegrate quickly under the tongue and can be absorbed into the blood through the sublingual venous plexus. Its key pharmacologic activities are anti-inflammations and free radicals scavenging, thus minimizing the cascading injury caused by AIS and protecting brain cells. Such unique sublingual formulation is expected to increase the flexibility of stroke treatment and improve medication compliance.

The Sanbexin® sublingual tablets is expected to form a sequential therapy with the Company's marketed Sanbexin® (Edaravone and Dexborneol Concentrated Solution for Injection) and 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 the National Medical Products Administration of China (the "**NMPA**"). The first indication is for the improvement of the neurological symptoms, activities of the daily living and dysfunction caused by AIS. On November 28, 2023, the new indication of Sanbexin® sublingual tablets was approved by the NMPA, which was intended for the clinical trials of the preventive treatment of post stroke cognitive impairment (PSCI) among AIS patients.

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, February 20, 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.