

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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 IN RELATION TO
THE PUBLICATION OF CLINICAL STUDY DATA
FOR SANBEXIN™ (EDARAVONE AND
DEXBORNEOL CONCENTRATED SOLUTION
FOR INJECTION) IN THE MEDICAL JOURNAL 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 advancement of the Group.

The board of directors of the Company (the “**Board**”) is pleased to announce that data from the result of TASTE Trial relating to Sanbexin™ (edaravone and dexborneol concentrated solution for injection), an innovative drug developed by the Company, was published in STROKE, a leading international authoritative medicine journal, on February 16, 2021 (US time). The article is titled “Edaravone Dexborneol Versus Edaravone Alone for the Treatment of Acute Ischemic Stroke: A Phase III, Randomized, Double-Blind, Comparative Trial” and the corresponding author of the article is Professor Wang Yongjun of Beijing Tiantan Hospital, Capital Medical University.

The Phase III clinical trial (TASTE Trial) of edaravone and dexborneol concentrated solution for injection included a total of 1,200 subjects and was completed at 48 clinical centres in China. The clinical trial data showed that edaravone and dexborneol concentrated solution for injection has better efficacy and comparable safety as compared to edaravone injection.

Subjects in the clinical trial were randomised and double-blinded in a 1:1 ratio to the edaravone and dexborneol group (30mg/7.5mg, BID) and the edaravone group (30mg, BID), both groups being treated for 14 consecutive days on the basis of the usual clinical treatment. The data showed that.

- (1) Primary efficacy endpoint: the proportion of subjects with an mRS score of 0 to 1 in the edaravone and dexborneol group at the 90th day was substantially higher than that in the edaravone group, being 67.18% and 58.97% respectively (dominance ratio OR = 1.42, 95% CI: 1.12 ~ 1.81, P = 0.004);
- (2) Safety: Safety and tolerability were good, with the incidences of adverse events and serious adverse events being comparable between the two groups.

ABOUT SANBEXIN™ (EDARAVONE AND DEXBORNEOL CONCENTRATED SOLUTION FOR INJECTION)

Sanbexin™ (edaravone and dexborneol concentrated solution for injection) is an innovative drug developed by the Company. It is a compound of edaravone and dexborneol with a proven ratio of 4:1. Edaravone is an antioxidant and a free radical scavenger which scavenges hydroxyl free radical (OH), nitric oxide free radicals (NO) and peroxynitrite anion (ONOO-); while dexborneol is a bicyclic monoterpene which could inhibit the production or expression of pro-inflammatory cytokines such as TNF- α and interleukin-1 β as well as inflammation-related proteins such as cyclo-oxygenase-2 and derived or induced nitric oxide synthase. With its dual mechanism of action, edaravone and dexborneol concentrated solution for injection scavenges free radicals, inhibits inflammatory response and improves the permeability in blood-brain barrier, minimizing brain injury or impairment caused by acute ischemic stroke. Compared with edaravone injection, the time window of edaravone and dexborneol concentrated solution for injection for new acute ischemic stroke treatment was extended from 24 hours to 48 hours. Edaravone and dexborneol concentrated solution for injection has obtained NMPA approval in July 2020. Sanbexin™ (edaravone and dexborneol concentrated solution for injection) has been launched by the Company in China in August 2020 and included in the new Catalogue of NRDL (National Reimbursement Drug List) on 28 December 2020.

ABOUT THE COMPANY

The Company is a company engaged in the R&D, production and commercialization of pharmaceuticals with the national key laboratory of translational medicine and innovative pharmaceuticals. The Company has a diversified product portfolio in strategically focused therapeutic areas, including, (i) oncology, (ii) central nervous system diseases and (iii) autoimmune diseases, with leading positions in their respective therapeutic segments and/or established track record. The Company continues to source innovative therapies globally and established extensive strategic partnership with several multinational companies.

By order of the Board of
Sincere Pharmaceutical Group Limited
Mr. Ren Jinsheng
Chairman and executive Director

Hong Kong, February 17, 2021

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