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

NEW DRUG APPLICATION (NDA) OF DEUNOXAVIR MARBOXIL TABLETS WAS ACCEPTED 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 regarding the latest business development of the Group.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that, on March 15, 2025, the new drug application ("**NDA**") of Deunoxavir Marboxil Tablets, an anti-influenza drug, jointly developed by the Group and Jiaxing AnDiCon Biotech Co., Ltd.* (嘉興安帝康生物科技有限公司) ("**AnDiCon**"), was accepted by the National Medical Products Administration (中國國家藥品監督管理局) of China (NMPA), Deunoxavir Marboxil Tablets are for treating uncomplicated influenza A and B in adults and adolescents.

ABOUT DEUNOXAVIR MARBOXIL

Deunoxavir Marboxil is an endonuclease inhibitor for influenza polymerase acidic (PA) protein. As shown in the research, Deunoxavir Marboxil demonstrates several benefits, including the absence of central nervous system side effects, no effect of food intake on oral drug absorption and higher safety dose. The entire oral dose of Deunoxavir Marboxil Tablets is merely "one tablet" and is capable of stopping influenza (the "**Influenza**") virus replication in 24 hours, having a prospect of bringing great convenience to a large number of patients, including child patients.

On October 10, 2023, the Group entered into a cooperation agreement (the "**Agreement**") with AnDiCon in relation to Deunoxavir Marboxil (the "**Product**"). Pursuant to the Agreement, the Group obtained the exclusive commercialization rights of the Product in China for indications related to the Influenza.

The results of phase II/III clinical study of Deunoxavir Marboxil indicated that as compared with the placebo group, the median time of all the Influenza symptoms relief achieved 26.543% improvements and such difference was statistically meaningful ($P<0.0001$), while the safety level is line with the placebo group.

On February 21, 2024, children's granules of Deunoxavir Marboxil received the Clinical Approval and is currently initiating phase III clinical trials, aiming at evaluating the safety, pharmacokinetics and efficacy of children's granules of Deunoxavir Marboxil among child patients of 2 to 11 years old with the Influenza. On January 12, 2025, the phase III clinical trial of children's granules of Deunoxavir Marboxil completed the Last-Patient-In (LPI). On February 27, 2025, children's granules of Deunoxavir Marboxil has obtained the Clinical Trial Approval issued by the NMPA, which is intended for commencing the clinical trial for post-exposure prevention of influenza type A and B among population aged 2 years old and above.

ABOUT ANDICON

Led by a number of academicians, the scientific and technological innovation team of AnDiCon focuses on the fields of respiratory system, anti-infection and analgesia. AnDiCon forged a group of academic high-level talents who are precise, efficient and pragmatic in different stages of new drug development, such as the design and synthesis of innovative drugs, research and application of DMPK technology as well as research and development of high-end preparations applicable to special populations, and established a new drug R&Dsystem based on metabolic differentiation leveraging on its DMPK platform.

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 neuroscience, anti-oncology, 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, March 17, 2025

* *For indicative purpose only*

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.