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# **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 CONDITIONAL MARKETING OF COSELA® (TRILACICLIB HYDROCHLORIDE FOR INJECTION) IN CHINA 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 ("Directors", and each a "Director") of the Company is pleased to announce that, on July 12, 2022, the marketing of COSELA® (generic name: Trilaciclib hydrochloride for injection) in China, which is a cyclin-dependent kinase CDK4/6 inhibitor developed by the Group in collaboration with G1 Therapeutics, INC. ("G1"), has obtained the conditional approval by the National Medical Products Administration (國家藥品監督管理局) (the "NMPA"), the product is approved to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen for extensive-stage small cell lung cancer ("ES-SCLC").

COSELA® is the first therapy with function of protecting existing bone marrow when administered prior to treatment with chemotherapy. According to the published results summary of many clinical studies of ES-SCLC, COSELA® can significantly reduce the duration of severe neutropenia in the first cycle of chemotherapy, and lower the incidence of severe neutropenia overall, Grade 3/4 anemia, Grade 3/4 anemia thrombocytopenia, and red blood cell transfusions, etc. Upon its marketing in China, COSELA® will protect more cancer patients by reducing the damage caused by chemotherapy to bone marrow hematopoietic stem/progenitor cells and immune cells, thereby filling a gap in the market.

# ABOUT COSELA®

COSELA® received a "Breakthrough Therapy" designation by the US Food and Drug Administration (FDA) and marketed in the US since February 2021. In August 2020, the Group reached an exclusive authorization contract with G1 to obtain COSELA®'s development and commercialization interests of all indications in Greater China. In January, April and June 2021, the Group has carried out three phase III clinical trials for ES-SCLC, metastatic colorectal cancer and triple negative breast cancer, respectively. In November 2021, the NMPA accepted the New Drug Application (NDA) by COSELA® for registration and marketing of overseas manufactured drugs. In December 2021, the drug was granted in the priority review. In February 2022, the COSELA® reached the primary endpoint for its use for ES-SCLC critical phase III clinical trials (TRACES study), the main research results will be published at 2022 World Conference on Lung Cancer (WCLC).

### **ABOUT G1**

G1 is a commercial-stage biopharmaceutical company focused on the discovery, development and delivery of next-generation therapies designed to improve the lives of cancer patients.

### ABOUT THE COMPANY

The Company is an innovation and R&D-driven pharmaceutical company. It has established a National Key Laboratory of Translational Medicine and Innovative Drug Development. The Company focuses on three therapeutic areas, oncology, central nervous system and autoimmune diseases, 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." Leveraging its R&D capability and commercialization excellence, the Company has built a market-leading product portfolio in China. Its vigorous in-house R&D efforts and extensive R&D collaborations have made it a strategic cooperation partner with world leading innovative companies and research institutes.

There is no assurance that COSELA® will ultimately be successfully marketed by the Company. The shareholders and potential investors of the Company shall exercise caution when dealing in the shares of the Company.

By order of the Board
Simcere Pharmaceutical Group Limited
Mr. Ren Jinsheng

Chairman and executive Director

Hong Kong, July 13, 2022

As at the date of this announcement, the Board comprises Mr. REN Jinsheng as the Chairman and executive Director, 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.