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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  
REGULAR APPROVAL OF COSELA<sup>®</sup>  
(TRILACICLIB HYDROCHLORIDE FOR INJECTION) APPROVED BY  
THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION OF CHINA**

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 October 27, 2023, COSELA<sup>®</sup> (Trilaciclib Hydrochloride for Injection), an innovative drug of the Group in the field of oncology, has fulfilled the supplemental application conditions and has been approved by the National Medical Products Administration of China (國家藥品監督管理局) (the “**NMPA**”) to change from conditional approval to regular approval. The indication is to decrease the incidence of chemotherapy-induced myelosuppression when administered prior to a platinum/etoposide-containing regimen for patients with extensive-stage small cell lung cancer (“**ES-SCLC**”), who have not previously received systemic chemotherapy.

## **ABOUT COSELA®**

COSELA® is a cyclin-dependent kinase CDK4/6 inhibitor developed by the Group in collaboration with G1 Therapeutics, INC. (“G1”) and is the first-in-class innovative drug to protect bone marrow when administered prior to treatment with chemotherapy. The results of several published ES-SCLC clinical studies show that, COSELA® can significantly reduce the duration of severe neutropenia in Cycle 1, and lower the incidence of severe (Grade 4) neutropenia, Grade 3/4 anemia, Grade 3/4 thrombocytopenia and red blood cell transfusions, etc. COSELA® received a “Breakthrough Therapy” designation by the US FDA and marketed in the US in February 2021. COSELA® has been recommended by multiple key guidelines such as the National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO), Chinese Society of Clinical Oncology (CSCO).

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. On July 12, 2022, COSELA® obtained the conditional approval by the NMPA to market in China. On January 14, 2023, a supplemental application of the Group in relation to the change of production site of COSELA® was accepted by the NMPA, so as to transfer the commercial supply of COSELA® to domestic production enterprises as soon as possible. On August 14, 2023, the marketing application of the new indication of COSELA® was accepted by the NMPA, expanding the application of COSELA® in patients with ES-SCLC who receive topotecan-containing regimen.

## **ABOUT G1**

G1 is a biopharmaceutical company at commercial stage 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 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  
**Sincere Pharmaceutical Group Limited**  
**Mr. Ren Jinsheng**  
*Chairman and Chief Executive Officer*

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