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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

THE CLINICAL TRIAL APPROVAL FOR SIM0237(ANTI-PD-L1/IL-15 BISPECIFIC ANTIBODY) ISSUED 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 December 23, 2022, SIM0237 for injection, an anti-PD-L1/IL-15 bispecific antibody independently developed by the Group, has obtained the Clinical Trial Approval issued by the National Medical Products Administration (NMPA) (國家藥品監督管理局) of China, which is intended to treat advanced solid tumors. Previously, a Study May Proceed letter was issued by the U.S. Food and Drug Administration (FDA) on October 27, 2022 for the IND application of SIM0237.

ABOUT SIM0237

SIM0237 is an anti-PD-L1 monoclonal antibody fused with IL-15/IL-15R α sushi protein and developed in-house by utilizing the Group’s protein engineering platform. It can block the PD-1/PD-L1 immunosuppressive pathway via binding to PD-L1 and activate the immune system through its IL-15 part, thus playing a synergistic role of relieving immunosuppression and boosting the immune system to exhibit antitumor effect. Preclinical studies showed that SIM0237 is more effective than PD-L1 or IL-15 mono treatment in mouse tumor models, suggesting a high potential for clinical development.

ABOUT THE COMPANY

The Company is an innovation and R&D-driven pharmaceutical company. It has established a State 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. 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, December 27, 2022

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