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 SIM0500 FOR INJECTION (A HUMANIZED GPRC5D-BCMA-CD3 TRISPECIFIC ANTIBODY) WAS GRANTED U.S. FDA FAST TRACK DESIGNATION

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 April 9, 2024, Beijing Time, SIM0500 for injection, a humanized GPRC5D-BCMA-CD3 trispecific antibody, which is a new investigational anti-tumor drug independently developed by the Group, has been granted a Fast Track Designation by the U.S. Food and Drug Administration ("**FDA**") for patients with multiple myeloma, who are refractory to, or intolerant of, established therapies known to provide clinical benefit and have received ≥3 prior lines of therapy including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD) and an anti-CD38 monoclonal antibody.

ABOUT FAST TRACK DESIGNATION

The FDA Fast Track Designation is an approach to expedite development and review of potential medicines. A drug which is granted Fast Track Designation is intended to treat a serious condition and address unmet medical need, and may be the first therapy for a specific condition, or offer clinically significant advantages over available therapies, or benefit patients who are unresponsive to or intolerant of available therapies.

ABOUT SIM0500

SIM0500 is a humanized GPRC5D-BCMA-CD3 trispecific antibody, which is a potential best-in-class (BIC) drug for the treatment of multiple myeloma based on the preclinical data. Through the research and development platform of multispecific antibody drugs with the Group's own T-cell engagers, SIM0500 is a tumor-targeted T-cell activating drug, composed with the Group's self-developed CD3 antibody with the feature activated by low affinity and high target activation and the antibody with anti-tumor associated antigen. It has the advantages of excellent tumor-killing effect and good tolerance. SIM0500 can potentially overcome the drug resistance caused by the existing treatments, and show excellent anti-tumor activity in various animal pharmacodynamic models with different expression levels of BCMA or GPRC5D and has multiple advantages, such as low effective dose and no recurrence of tumors after drug withdrawal.

On March 9 and March 12, 2024, the Investigational New Drug (IND) application of SIM0500 has been approved by the FDA and the National Medical Products Administration of China (NMPA), respectively.

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
Simcere Pharmaceutical Group Limited
Mr. Ren Jinsheng
Chairman and Chief Executive Officer

Hong Kong, April 9, 2024

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.