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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 NEW INDICATION OF SIM0237 FOR INJECTION (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 (the “**Directors**”) of the Company is pleased to announce that, on October 15, 2023, a new indication of 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 (國家藥品監督管理局) (the “**NMPA**”) of China, which is intended to be applicable to patients with non-muscle invasive bladder cancer (NMIBC).

#### **ABOUT SIM0237**

SIM0237 is an anti-PD-L1 monoclonal antibody fused with IL-15/IL-15R  $\alpha$  sushi protein and developed in-house by utilizing the Group’s self-owned 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 dual 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.

Application for new-drug clinical trial of indication of SIM0237 for treating advanced solid tumors was approved by the U.S. Food and Drug Administration and China's NMPA on October 27, 2022 and December 23, 2022, respectively, and, at present, the relevant multi-regional clinical trial (MRCT) of the indication is in progress concurrently in China and the U.S..

## **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 16, 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.*