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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 SIM0505 (CDH6 ANTIBODY-DRUG CONJUGATE)

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 regarding the latest business development of the Group.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that, on January 2, 2025, SIM0505, a CDH6 Antibody-Drug Conjugate (ADC) which is an anti-tumor drug candidate 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) of China, which is intended for commencing the clinical trial for advanced solid tumors. On December 28, 2024, the Investigational New Drug (IND) application of SIM0505 was approved by the U.S. Food and Drug Administration (FDA).

ABOUT SIM0505

CDH6, a type II classical cadherin, is highly expressed in a variety of tumors but with very limited expression in normal tissues. SIM0505 is a CDH6-targeting ADC molecule developed by the Group, which consists of CDH6 monoclonal antibody specifically binding to tumor cells and the Group’s proprietary camptothecin derivative toxin, conjugated by a linker. By combining the tumor-specific targeting antibody with the high-efficiency killing effect of toxin molecules, SIM0505 can specifically target tumor cells and reduce the toxic side effects compared to traditional chemotherapies. Such ADC is intended for the treatment of malignant tumors such as ovarian and renal cancer.

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, January 6, 2025

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