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

APPROVAL FOR MARKETING OF YINGMULE® IN CHINA 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 September 3, 2026, the domestic Class 1 biological innovative drug Culevibart Injection (trade name: Yingmule®), developed under the strategic cooperation between the Group and Reyoung (Shandong) Biopharmaceutical Co., Ltd. ("**Reyoung Bio**") was approved for marketing in China by the National Medical Products Administration (NMPA) of China. It is indicated for newborns and infants born at or after 35 weeks of gestational age who are entering or born during their first respiratory syncytial virus ("**RSV**") epidemic season, to prevent lower respiratory tract infections caused by RSV, excluding children with chronic lung disease CLD, including bronchopulmonary dysplasia (BPD) or clinically significant congenital respiratory abnormalities. On August 20, 2026, the Group entered into a strategic cooperation with Reyoung Bio, obtaining the exclusive commercialization rights of Yingmule® in Greater China.

ABOUT CULEVIBART

Culevibart is a recombinant human IgG1κ monoclonal antibody, which primarily provides passive immunity by targeting epitope II of the respiratory syncytial virus F protein. Culevibart achieves half-life extension of the antibody through Fc segment engineering, providing newborns and infants with continuous protection covering the entire RSV epidemic season via a single intramuscular injection. As a passive immunization agent, Culevibart can rapidly reach protective antibody levels upon administration to quickly establish a protective barrier, making it suitable for the broad infant and toddler population currently lacking active immunization options.

The pivotal Phase III study supporting this approval is a multicenter, randomized, double-blind, placebo-controlled clinical study. Trial data showed that at 150 days post-dose, compared with placebo, the efficacy of Culevibart against RSV-caused lower respiratory tract infections requiring medical intervention (outpatient, emergency or hospitalization) was 85.32%, and the efficacy against RSV infection-induced hospitalization was 83.27%. At 240 days post-dose, compared with placebo, the efficacy of Culevibart against RSV-caused lower respiratory tract infections requiring medical intervention (outpatient, emergency or hospitalization) caused by RSV was 82.04%, and the efficacy against RSV infection-induced hospitalization was 78.44%. In addition, a Phase IIIb study targeting infants and toddlers aged 1 to 2 years is ongoing to further expand the applicable age range.

ABOUT REYOUNG BIO

Reyoung (Shandong) Biopharmaceutical Co., Ltd. specializes in the R&D and commercialization of antibody-based biologic drugs, with a core focus on passive immunization for prophylaxis and treatment of infectious diseases, alongside exploratory programs in tumor immunotherapy. Reyoung Bio utilizes proprietary technology platforms and the identification and screening of rare elite samples to discover and develop first-in-class antibody drugs characterized by high specificity, high affinity, and broad-spectrum activity. Reyoung Bio is committed to delivering differentiated and innovative solutions for major diseases.

ABOUT THE GROUP

The Company is an innovation and R&D-driven pharmaceutical company. The Group focuses on the therapeutic areas of neuroscience, anti-oncology, 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 "for patients, for life". 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, September 3, 2026

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