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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

NEW DRUG APPLICATION (NDA) OF ZEMPROCITINIB FOR THE TREATMENT OF RHEUMATOID ARTHRITIS WAS ACCEPTED 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 the new drug application for zemprocitinib, a highly selective, second-generation JAK1 inhibitor jointly developed by the Group and Lynk Pharmaceuticals (Zhejiang) Co., Ltd. ("**Lynk Pharmaceuticals**") for the treatment of moderate-to-severe active rheumatoid arthritis (RA), has been formally accepted by the National Medical Products Administration. This is the second indication for zemprocitinib to enter the registration review phase in China, following its indication for adult moderate-to-severe atopic dermatitis.

This application is primarily based on the positive results of a multicenter, randomized, double-blind, placebo-controlled Phase III clinical study conducted in China. Led by Professor Zeng Xiaofeng of Peking Union Medical College Hospital, the study enrolled 430 patients with moderate-to-severe active RA who had previously experienced inadequate response or poor tolerability to biologics. The results showed that, for both the primary endpoint and key secondary endpoints, zemprocitinib demonstrated a statistically significant ($p < 0.0001$) therapeutic advantage over the placebo group, with good overall safety and tolerability.

Long-term follow-up data further confirmed the sustained benefits of zemprocitinib. Among patients who continued treatment through Week 76, the response rates for the American College of Rheumatology 20% improvement criterion (ACR20) and 50% improvement criterion (ACR50) remained at 91.8% and 80.5%, respectively; the ACR70 response rate further increased from 52.5% at Week 52 to 62.4% at Week 76.

In addition, zemprocitinib demonstrated sustained and consistent efficacy in terms of indicators such as disease activity scores (DAS28-CRP≤3.2) and improvements in physical function (HAQ-DI improvement≥0.22).

ABOUT ZEMPROCITINIB

Zemprocitinib is a highly selective, oral, second-generation JAK1 inhibitor independently developed by Lynk Pharmaceuticals. It is currently being developed for the treatment of inflammatory and autoimmune diseases, including RA, atopic dermatitis ("**AD**") and ankylosing spondylitis ("**AS**"). The Group entered into a collaboration with Lynk Pharmaceuticals in March 2022 and obtained the exclusive commercialization rights to zemprocitinib in Greater China for the treatment of RA and AS. In November 2026, the Group further expanded the collaboration with Lynk Pharmaceuticals in respect of zemprocitinib, under which the Group has obtained the exclusive commercialization rights to zemprocitinib in Greater China for the treatment of adult moderate-to-severe AD and other dermatological indications.

ABOUT THE GROUP

The Company is an innovation and R&D-driven pharmaceutical company and the Group has established a "State Key Laboratory of Neurology and Oncology Drug Development". 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, November 6, 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; Mr. SONG Ruilin, Mr. WANG Jianguo, Mr. WANG Xinhua and Mr. SUNG Ka Woon as the independent non-executive Directors.