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 QUVIVIQ® 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 June 20, 2025, the new drug application ("**NDA**") of QUVIVIQ® (daridorexant hydrochloride tablets), an anti-hypnotic drug jointly developed by the Group and Idorsia Pharmaceuticals Ltd. ("**Idorsia**"), was approved for marketing in China by the National Medical Products Administration ("**NMPA**") of China. The indication of QUVIVIQ® is for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance and QUVIVIQ® has not been designated as a controlled substance.

ABOUT QUVIVIQ®

QUVIVIQ® is a dual orexin receptor antagonist ("**DORA**"). Unlike traditional sedative-hypnotic drugs that promote sleep by sedating the brain, QUVIVIQ® works by blocking the binding of wake-promoting orexin neuropeptides (orexin A and orexin B) to their receptors. As a result, QUVIVIQ® reduces wake drive and facilitates the onset of sleep, decreases wake time after sleep onset, and extends total sleep duration, without altering sleep architecture. Clinical study results have shown that QUVIVIQ® has a favorable safety and tolerability profile, with no evidence of rebound insomnia, withdrawal symptoms, or drug abuse. In addition to improving nighttime sleep in adults with insomnia disorder, QUVIVIQ® also enhances daytime functioning. It is the only DORA insomnia medication approved by the European Medicines Agency (EMA) for improving daytime functioning. The Guidelines for the Diagnosis and Treatment of Insomnia Disorders in China (2nd Edition), published in 2025, strongly recommend QUVIVIQ® with Grade A evidence. Previously, QUVIVIQ® has been approved for marketing in 11 countries including the United States, the United Kingdom, Switzerland, and Canada, as well as in the Hong Kong SAR of China.

ABOUT IDORSIA

Headquartered near Basel, Switzerland – a European biotech-hub – Idorsia is specialized in the discovery, development and commercialization of small molecules to transform the horizon of therapeutic options. Idorsia has a 25-year heritage of drug discovery, a broad portfolio of innovative drugs in the pipeline, an experienced team of professionals covering all disciplines from bench to bedside, and commercial operations in Europe and North America – the ideal constellation for bringing innovative medicines to patients. Idorsia was listed on the SIX Swiss Exchange (ticker symbol: IDIA) in June 2017 and has over 750 highly qualified specialists dedicated to realizing its ambitious targets.

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 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, June 20, 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; and Mr. SONG Ruilin, Mr. WANG Jianguo, Mr. WANG Xinhua and Mr. SUNG Ka Woon as the independent non-executive Directors.