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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

APPROVAL FOR MARKETING OF ENZESHU® 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 July 3, 2025, ENZESHU® (Suvemcitug for injection), a category 1 biological new drug, was approved for marketing in China by the National Medical Products Administration (NMPA) of China (Approval number: S20250037, Approval date: June 30, 2025). ENZESHU® is indicated for the treatment of recurrent ovarian cancer, fallopian tube cancer, or primary peritoneal cancer in combination with paclitaxel, liposomal doxorubicin, or topotecan in adults who have received no more than one systemic therapy after platinum resistance. There are no anti-angiogenic therapies approved in China for the treatment of platinum-resistant ovarian cancer (PROC), particularly for patients with prior exposure to anti-angiogenic treatment, representing a significant unmet clinical need. The approval of ENZESHU® is expected to provide a much-needed new therapeutic option for patients with platinum-resistant ovarian cancer in China.

ABOUT ENZESHU®

ENZESHU® is a next-generation recombinant humanized anti-vascular endothelial growth factor (“**VEGF**”) monoclonal antibody developed by the Group and Pyxis Oncology, Inc.. By potently blocking the binding of VEGF to its receptor, ENZESHU® inhibits tumor angiogenesis, thereby achieving an anti-tumor effect. With a unique molecular design featuring a differentiated VEGF-binding epitope, ENZESHU® has demonstrated significantly greater inhibitory activity against the binding of VEGF to its receptor (VEGFR2) compared to bevacizumab, as well as stronger suppression of human vascular endothelial cell proliferation. Preclinical studies have shown that ENZESHU® exhibits enhanced biological activity and superior tumor-inhibitory effects relative to bevacizumab at the same dosage across multiple tumor models. The randomized double-blind placebo controlled registrational Phase III clinical trial of ENZESHU® (the SCORES study) demonstrated significant benefits in the primary efficacy endpoint of progression-free survival (“**PFS**”) assessed by the Blinded Independent Review Committee (BIRC) as well as investigator-assessed PFS. Median PFS was extended from 2.73 months to 5.49 months, with a hazard ratio (“**HR**”) of 0.46 (0.35,0.60), $p < 0.0001$. For the key secondary endpoint, overall survival (“**OS**”) was prolonged in the treatment group compared to the control group, with a 23% reduction in the risk of death (HR 0.77, $p = 0.0304$). ENZESHU® is the first anti-angiogenic therapy to achieve a significant OS benefit in patients with platinum-resistant ovarian cancer.

ABOUT PYXIS ONCOLOGY, INC.

Pyxis Oncology, Inc. is a clinical stage company focused on defeating difficult-to-treat cancers. Pyxis Oncology, Inc. is efficiently building next-generation therapeutics that hold the potential for monotherapy and combination indications.

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
Sincere Pharmaceutical Group Limited
Mr. Ren Jinsheng
Chairman and Chief Executive Officer

Hong Kong, July 3, 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.