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 PHASE III CLINICAL STUDY OF SUVEMCITUG FOR INJECTION IN THE TREATMENT OF PLATINUM-RESISTANT OVARIAN CANCER HAS SUCCESSFULLY MET THE PRIMARY STUDY ENDPOINT

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 January 3, 2024, the phase III clinical trial of Suvemcitug for injection combined with chemotherapy (the "**Experimental Group**") versus placebo combined with chemotherapy (the "**Placebo Group**") in patients with recurrent, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer (NCT04908787) (the "**SCORES Study**") has met the primary endpoint.

The results include the final analysis of progression-free survival (the "**PFS**") as the primary endpoint, the first analysis of overall survival (the "**OS**") as the key secondary endpoint, and the safety analysis. The results showed: (1) the SCORES study has met the primary endpoint PFS which is assessed by the Blinded Independent Review Committee (BIRC) according to the RECIST 1.1 criteria. Compared with the Placebo Group, the improvement of PFS in the Experimental Group is both statistically and clinically significant, and Suvemcitug has shown consistent PFS benefits among all pre-defined sub-groups. The PFS benefit of the Experimental Group evaluated by the researchers is consistent with those evaluated by BIRC; (2) the OS data are immature, but there is a trend of OS benefit in the Experimental Group; (3) the safety is manageable, no new safety signals are identified. The study results are expected to be released in academic journals or conferences in the future.

The Group plans to submit a New Drug Application (NDA) for Suvemcitug for injection in the treatment of platinum-resistant ovarian cancer to the National Medical Products Administration (NMPA) of China in the near future.

ABOUT THE SCORES STUDY

The SCORES study is a multi-center, randomized, double-blind and placebo-controlled phase III clinical trial to evaluate the efficacy and safety of Suvemcitug combined with chemotherapy in patients with recurrent, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer. This study was led by the Cancer Hospital Chinese Academy of Medical Sciences, and has enrolled 421 patients at 55 research centers in China. The SCORES study completed the first patient in (FPI) on June 11, 2021 and completed all planned enrollment on June 27, 2023. The success of this study demonstrates the clinical value of Suvemcitug, which is expected to bring new treatment options for cancer patients.

ABOUT SUVEMCITUG

Suvemcitug is a new-generation recombinant humanized anti-VEGF rabbit monoclonal antibody developed by the Group and Apexigen, Inc. (the "**Apexigen**") (now part of Pyxis Oncology, Inc.) Pre-clinical studies have shown that Suvemcitug has higher affinity and anti-tumor efficacy than Bevacizumab at the same dose in multiple tumor models. The phase Ib clinical studies of Suvemcitug conducted in China for the treatment of ovarian cancer preliminary demonstrated its favorable safety profile and efficacy signals. An open-label, multi-cohort and multi-center phase II clinical trial commenced simultaneously by the Group evaluates the efficacy and safety of Envafolimab (PD-L1) in combination with Suvemcitug with or without chemotherapy in patients with advanced solid tumors, and the results of hepatocellular carcinoma, non-small cell lung cancer and colorectal cancer cohort published in 2023 ESMO conference showed that, Envafolimab in combination with Suvemcitug has good anti-tumor activity and manageable safety profile in solid tumors.

ABOUT APEXIGEN

Apexigen is a clinical-stage biopharmaceutical company focused on discovering and developing innovative antibody therapeutics for oncology. On August 23, 2023, Apexigen is acquired by Pyxis Oncology, Inc. (a Nasdaq listed public company in the United States – Nasdaq: "**PYXS**"). Pyxis Oncology, Inc. is a clinical stage company focused on defeating difficult-to-treat cancers, and is efficiently building next-generation therapeutics that hold the potential for mono and combination therapies.

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

Hong Kong, January 4, 2024

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.