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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 ON THE MARKETING OF ENLITUO (CETUXIMAB BETA INJECTION) 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, ENLITUO (恩立妥®) (cetuximab beta injection), which is collaborated by the Group and Mabpharm Limited (“**Mabpharm**”), has recently been approved for marketing in China by the National Medical Products Administration of China (the “**NMPA**”), the indication of which is to be used for the first-line therapy of RAS/BRAF wild-type metastatic colorectal cancer (“**mCRC**”) in combination with FOLFIRI regimen.

ABOUT ENLITUO

ENLITUO (product code: CMAB009) is a recombinant anti-EGFR chimeric monoclonal antibody and is a category 2.4 improved biologics. It is prepared using a specific expression process, effectively avoiding glycosylation modification that may lead to hypersensitivity. Its safety and efficacy has been confirmed from the results of various completed clinical trials. In March 2023, the drug marketing application of ENLITUO was accepted by the NMPA. On August 18, 2023, the Group entered into a cooperation agreement with Mabpharm, pursuant to which the Group obtained the exclusive commercial rights in respect of ENLITUO in Chinese mainland.

ENLITUO is the first anti-epidermal growth factor receptor (“**EGFR**”) monoclonal antibody innovative drug developed in China with independent intellectual property rights which has been approved by the NMPA for first-line therapy of mCRC. The successful launch of ENLITUO will provide high quality and affordable biological targeted remedy for Chinese patients with tumor.

ABOUT MABPHARM

Mabpharm (stock code: 2181) focuses on the R&D of monoclonal antibodies and has an experienced R&D team, multiple core technologies, leading domestic large-scale antibody preparation system and excellent quality control system. Mabpharm strives to bring high quality and affordable innovative biologics through its efficient R&D system and low-cost pharmaceutical production capability to the market, and develops various therapeutic products by fully utilizing its extensive R&D experience.

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

Hong Kong, June 25, 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.