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ASCENTAGE PHARMA GROUP INTERNATIONAL

亞盛醫藥集團

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 6855)

Voluntary Announcement

Ascentage Pharma Establishes Cooperation with the US National Cancer Institute to advance the Clinical Development of Ascentage Pharma's Bcl-2/Bcl-xL inhibitor APG-1252

Ascentage Pharma Group International (the “Company” or “Ascentage Pharma”) is pleased to announce that the Company has entered into a Cooperative Research and Development Agreement (CRADA) with the US National Cancer Institute (NCI), part of the US National Institutes of Health (NIH), under which they will collaborate on the clinical and non-clinical development of Ascentage Pharma's novel dual inhibitor of BCL-2/BCL-xL proteins APG-1252 (Pelcitoclax).

Under the terms of the CRADA, Ascentage Pharma and the NCI will collaborate on a series of clinical trials to evaluate the safety and efficacy of APG-1252 in the treatment of solid tumors based upon anti-tumor activity observed in previous studies conducted by Ascentage Pharma. The NCI will also conduct a series of non-clinical correlative studies that focus on exploring the biologic activity of APG-1252, as well as combination studies of the compound with other targeted agents.

As data from the NCI-sponsored studies and other Ascentage-sponsored trials emerge, Ascentage and the NCI will carry out additional studies to support the clinical development of APG-1252.

About APG-1252 (Pelcitoclax)

APG-1252 (Pelcitoclax) is a novel, dual inhibitor of BCL-2 and BCL-xL proteins developed by Ascentage Pharma and was designed using a pre-drug strategy that improves its therapeutic index, decreases cell permeability, and reduces platelet toxicity. APG-1252 binds to BCL-2 and BCL-xL molecules with high affinity and demonstrates significantly potent anti-leukemic activity in preclinical models.

In a multi-center, open-label, dose escalation phase I study, the safety, pharmacokinetics, and preliminary anti-tumor activity of APG-1252 were evaluated in patients with metastatic small-cell lung cancer (SCLC) or other solid tumors. To overcome treatment resistance, combining APG-1252 with other therapies is also a potentially viable clinical strategy. Currently, APG-1252 is being evaluated in combination with paclitaxel in relapsed or refractory SCLC.

About Ascentage Pharma

Ascentage Pharma is a China-based, globally focused, clinical-stage biotechnology company engaged in developing novel therapies for cancers, CHB (Chronic hepatitis B), and age-related diseases. On October 28, 2019, Ascentage Pharma became listed on the Main Board of The Stock Exchange of Hong Kong Limited with the stock code: 6855.HK.

Ascentage Pharma has its own platform for developing therapeutics that inhibit protein-protein interactions to restore apoptosis or programmed cell death. The company has built a pipeline of eight type I small molecule clinical drug candidates which have entered the clinical development stage, including novel, highly potent Bcl-2 inhibitors, as well as candidates aimed at IAP and MDM2-p53 pathways, and next-generation tyrosine kinase inhibitors (TKIs). Ascentage Pharma is also the only company in the world with active clinical programs targeting all key apoptosis regulators. The Company is conducting more than 40 Phase I/II clinical trials in China, the US and Australia. HQP1351, the Company's core drug candidate developed for the treatment of drug-resistant chronic myeloid leukemia (CML), has been granted an Orphan Drug Designation (ODD) and a Fast Track Designation (FTD) by the US FDA, and a New Drug Application (NDA) for the drug candidate has been submitted and subsequently granted Priority Review by the Center for Drug Evaluation (CDE) in China. As at the date of this announcement, Ascentage Pharma has obtained a total of eleven ODDs from the US FDA for four of the Company's investigational drug candidates.

Leveraging its robust research and development capabilities, Ascentage Pharma has built a portfolio of global intellectual property rights, and entered into global partnerships with numerous renowned biotechnology and pharmaceutical companies and academic institutes such as UNITY Biotechnology, MD Anderson Cancer Center, Mayo Clinic, Dana-Farber Cancer Institute, MSD, and AstraZeneca. The Company has built a talented team with global experience in the discovery and development of innovative drugs, and is setting up its world-class commercial manufacturing and sales & marketing teams. Ascentage Pharma aims to continuously strengthen its research and development capabilities and accelerate its clinical development programs to fulfil its mission of “addressing unmet clinical needs in China and around the world” for the benefit of more patients.

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: We cannot guarantee that we will be able to obtain further approval for, or ultimately market, APG-1252 successfully.

By order of the Board
Ascentage Pharma Group International
Dr. Yang Dajun
Chairman and Executive Director

Suzhou, People’s Republic of China, July 19, 2021

As at the date of this announcement, the Board of Directors of the Company comprises Dr. Yang Dajun as Chairman and executive Director, Dr. Wang Shaomeng, Dr. Tian Yuan, Dr. Lu Simon Dazhong and Mr. Liu Qian as non-executive Directors, and Mr. Ye Changqing, Dr. Yin Zheng, Mr. Ren Wei and Dr. David Sidransky as independent non-executive Directors.