亞盛醫藥
Ascentage Pharma

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 Announces CDE's Approval for the Phase II Pivotal Study in China of the Bcl-2 Inhibitor Lisaftoclax (APG-2575) for the Treatment of Relapsed/ Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Ascentage Pharma Group International (the "**Company**" or "**Ascentage Pharma**") is pleased to announce that the Phase II pivotal study (the APG2575CC201 study) of the novel Bcl-2 selective inhibitor under the development of the Company, lisaftoclax (APG-2575), for the treatment of relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (R/R CLL/SLL) has been approved by the Center for Drug Evaluation (CDE) in China.

APG2575CC201 is a single-arm, open-label, Phase II pivotal clinical study on R/R CLL/SLL patients designed to evaluate the efficacy and safety of APG-2575, with objective response rate (ORR) as the primary endpoint. Based on existing safety and efficacy data of APG-2575, the CDE has agreed that results from the APG2575CC201 study can be used to support the future New Drug Application for the indication of R/R CLL/SLL.

APG-2575 is a novel, orally administered Bcl-2 selective inhibitor being developed by Ascentage Pharma. Lisaftoclax is designed to treat a variety of malignancies by selectively blocking Bcl-2 to restore the normal apoptosis process in cancer cells. It is the first China-developed Bcl-2 inhibitor entering clinical development in China. APG-2575 is being studied in multiple clinical studies in countries and regions including the U.S., China, Australia, and the European Union, for a range of hematologic malignancies and solid tumors such as CLL/SLL. At the 2021 American Society of Hematology (ASH) Annual Meeting, data of China studies of APG-2575 in the treatment of hematologic malignancies were released for the first time. These data demonstrated APG-2575's favorable tolerability and enormous therapeutic potential, without evidence of any tumor lysis syndrome (TLS). The six patients with CLL who received APG-2575 at 200 mg or higher doses achieved an ORR of 100% and one case of complete response (CR).

Globally, there are significant unmet medical needs in the treatment of CLL/SLL. Patients with R/R CLL/SLL, especially those who are refractory or resistant to immunotherapies, chemotherapies, and Bruton Tyrosine Kinase (BTK) inhibitors, commonly experience rapid disease progression and currently lack any effective treatment, thus representing an urgent need for an effective novel therapy.

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, and dual Bcl-2/Bcl-xL 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 three known classes of key apoptosis regulators. The Company is conducting more than 40 Phase I/II clinical trials in China, the US, Australia and Europe. Olverembatinib, the Company's core drug candidate developed for the treatment of drug-resistant chronic myeloid leukemia (CML), was granted Priority Review status and a Breakthrough Therapy Designation (BTD) by the Center for Drug Evaluation (CDE) of China National Medical Products Administration (NMPA), and is already approved for the indication. In addition, Olverembatinib has also been granted an Orphan Drug Designation (ODD) and a Fast Track Designation (FTD) by the US FDA, and an Orphan Designation by the EU. As at the date of this announcement, Ascentage Pharma has obtained a total of 12 ODDs from the US FDA and 1 ODD from the EU for four of the Company's investigational drug candidates. The Company has been designated for multiple major national R&D projects in China, including five Major New Drug Development Projects, one Enterprise Innovative Drug Incubator Base status, four Innovative Drug Research and Development Programs, and one Major Project for the Prevention and Treatment of Infectious Diseases.

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 leading biotechnology and pharmaceutical companies and research institutes such as UNITY Biotechnology, MD Anderson Cancer Center, Mayo Clinic, Dana-Farber Cancer Institute, MSD, and AstraZeneca. The Company has built a global and talented team with experience in the research and development of innovative drugs and clinical development, and is setting up its commercial manufacturing and sales and marketing teams with high standards. Ascentage Pharma aims to continuously strengthen its research and development capabilities and accelerate the clinical development progress of its product pipeline to fulfil its mission of "addressing unmet clinical needs of patients 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-2575 successfully.

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

Suzhou, People's Republic of China, December 13, 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.