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 First Patient Dosed in China in the Pivotal Phase II Study of Bcl-2 Selective Inhibitor Lisaftoclax (APG-2575) for the Treatment of R/R CLL/SLL

Ascentage Pharma Group International (the "**Company**" or "**Ascentage Pharma**") is pleased to announce that it has dosed the first patient in the pivotal Phase II study of the novel class 1 Bcl-2 selective inhibitor under the Company's development, lisaftoclax (APG-2575), for the treatment of relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma (R/R CLL/SLL) in China (APG2575CC201 study). Lisaftoclax is the second Bcl-2 inhibitor entering pivotal studies globally.

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

CLL/SLL is a hematologic malignancy caused by mature B-cell neoplasms and is among the most common lymphoid neoplasms in the Western world. In North America and Europe, the disease accounts for about 30% of all leukemia cases. In the US, the annual incidence of CLL was 21,250 in the year 2021 with 4,320 deaths (Surveillance, Epidemiology, and End Results (SEER) report), In China, 15,167 new cases of CLL were reported in 2020. With an aging population as well as dietary and lifestyle changes in China, CLL/SLL incidences are expected to rise, with more patients developing the condition at younger ages, and display aggressive disease progression.

Despite significant initial responses to current first-line treatments such as immunotherapies, chemotherapies, and Bruton's tyrosine kinase (BTK) inhibitors, relapse and drug-resistance remain major clinical challenges. Patients with R/R CLL/SLL commonly experience rapid disease progression and respond poorly to salvage treatments. Therefore, more clinical trials in relation to CLL should be initiated to explore effective novel therapeutic.

APG-2575 is a novel, orally administered small-molecule Bcl-2 selective inhibitor being developed by Ascentage Pharma to treat hematologic malignancies and solid tumors by selectively blocking the antiapoptotic protein Bcl-2 and hence restoring the normal apoptosis process in cancer cells. APG-2575 is the first China-developed Bcl-2 inhibitor entering clinical development in China, and the second entering pivotal studies globally. APG-2575 is being studied in multiple clinical studies in countries and regions including the China, the US, Australia, and Europe, for a range of solid tumors and hematologic malignancies such as CLL/SLL.

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 50 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 13 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, March 15, 2022

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.