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

Study of Ascentage Pharma's Olverembatinib Approved in Canada

Ascentage Pharma Group International (the "**Company**" or "**Ascentage Pharma**") is pleased to announce that that the Phase Ib clinical study of Ascentage Pharma's class 1 novel drug candidate, olverembatinib (HQP1351), for the treatment of patients with refractory chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) has been approved by Health Canada, making it Ascentage Pharma's first clinical study in the country.

This open-label, multicenter, randomized, global Phase Ib clinical study is designed to evaluate the safety, efficacy, pharmacokinetics (PK) and determine the recommended Phase II dose (RP2D) of olverembatinib in patients with CML in chronic-phase (CP), accelerated-phase (AP), or blast-phase (BP) or with Ph+ ALL, who are resistant or intolerant to at least two tyrosine kinase inhibitors (TKIs).

CML is a hematologic malignancy of the white blood cells. The commercialization of BCR-ABL TKIs has revamped the treatment of CML. However, acquired resistance to TKIs remains a major challenge in the treatment of CML. BCR-ABL tyrosine kinase mutations represent a key mechanism of acquired drug resistance. Currently, there is an urgent clinical need for a new generation drug.

Olverembatinib is a novel class 1, orally active, third-generation BCR-ABL inhibitor developed by Ascentage Pharma for the treatment of patients with CML resistant to first-and second-generation TKIs. It can effectively target a spectrum of BCR-ABL mutants, including the T315I mutation. As the first approved third-generation BCR-ABL inhibitor in China and the second globally, olverembatinib has global "best-in-class" potentials. The clinical results of olverembatinib in hematologic malignancies have been selected for oral presentations at the American Society of Hematology (ASH) Annual Meetings for four consecutive years since 2018, and was nominated for "Best of ASH" in 2019. As at the date of this announcement, olverembatinib has been granted one Fast Track designation and three Orphan Drug Designations from the US FDA for the treatment of CML, ALL, and acute myeloid leukemia (AML); and an Orphan Drug Designation by the EU, for the treatment of CML.

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 15 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, AstraZeneca and Pfizer. 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.

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

Suzhou, People's Republic of China, July 22, 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 and Dr. Lu Simon Dazhong as non-executive Directors, and Mr. Ye Changqing, Dr. Yin Zheng, Mr. Ren Wei and Dr. David Sidransky as independent non-executive Directors.