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's core drug candidate HQP1351 (Olverembatinib) Granted Orphan Designation by the European Commission for the Treatment of Chronic Myeloid Leukemia

Ascentage Group International (the "**Company**" or "**Ascentage Pharma**") is pleased to announce that the European Commission (EC) has granted the Company's novel class I drug candidate, Olverembatinib (HQP1351), an Orphan Drug Designation for the treatment of chronic myeloid leukemia (CML). This is the first Orphan Drug Designation granted to Ascentage Pharma's drug candidates in the European Union (EU), and the second Orphan Drug Designation granted to Olverembatinib globally, following the designation by the US Food and Drug Administration (FDA).

The term "orphan medicines" refers to pharmaceutical products developed for the prevention, diagnosis, and treatment of rare diseases or conditions. In the EU, Orphan Drug Designations are granted by the EC based on the opinions of the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA), and only those therapies treating life-threatening or chronically debilitating diseases or conditions affecting less than 5 in 10,000 people in the EU and represent huge unmet medical needs can be granted the Orphan Drug Designation. Moreover, designated drugs must be able to demonstrate through non-clinical and clinical data that it can potentially provide greater therapeutic benefit than existing therapies. The EU offers a range of incentives to encourage the development of designated orphan medicines. This Orphan Drug Designation for Olverembatinib would assist the drug candidate in enjoying great regulatory support in subsequent clinical development and commercialization in the European Union, including clinical protocol assistance, relevant fee reductions, and most importantly, 10 years of market exclusivity upon approval.

CML is a rare hematologic malignancy that has an annual incidence of 2.43 per 10,000[1] in the 27 member nations of the EU. BCR-ABL tyrosine kinase inhibitors (TKIs) have significantly improved the clinical management of CML. However, despite clinical benefits offered by the first-and second-generation BCR-ABL TKIs, many patients develop drug resistance. Such acquired resistance to TKIs is a major challenge in the treatment of CML. BCR-ABL kinase mutations represent a key mechanism of acquired drug resistance; T315I, which is one of the most-common drug-resistant mutation, occurs in about 25% of patients with drug-resistant CML. Patients with T315I-mutant CML are resistant to both first-and second-generation BCR-ABL inhibitors, hence presenting an urgent and high unmet medical need for third-generation BCR-ABL inhibitors to more effectively target the T315I mutation.

Olverembatinib is a novel class I new drug and a third-generation BCR-ABL TKI developed by Ascentage Pharma for the treatment of patients with CML resistant to first-and second-generation TKIs, which is highly efficacious in the CML patients harboring the T315I mutation. The New Drug Application (NDA) for Olverembatinib for the treatment of patients with chronic phase CML (CML-CP) or accelerated-phase CML (CML-AP) harboring the T315I mutation is currently under review in China. If approved by the National Medical Products Administration (NMPA), Olverembatinib has the hopes of becoming the first approved third-generation BCR-ABL TKI in China and the second globally. Previously, Olverembatinib was granted a Breakthrough Therapy Designation by the Center for Drug Evaluation (CDE) of NMPA for the treatment of patients with CML-CP resistant and/or intolerant to first-and second-generation TKIs. In the United States, Olverembatinib was granted an Orphan Drug Designation and Fast Track Designation by the US FDA. Furthermore, since 2018, the clinical data from Olverembatinib studies have been selected for oral presentations at the American Society of Hematology (ASH) Annual Meetings for four consecutive years, and was nominated for "Best of ASH" in 2019.

## 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. 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. As at the date of this announcement, Ascentage Pharma has obtained a total of 12 ODDs from the US FDA for 4 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 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, Olverembatinib successfully.

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

Suzhou, People's Republic of China, November 22, 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.*

Reference:
1. GBD 2019 Diseases and Injuries Collaborators Supplementary