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
Olverembatinib (HQP1351) of Ascentage Pharma is included in the list of "Priority Review"

Ascentage Pharma Group International（the "**Company**"or "**Ascentage Pharma**"）is pleased to announce that the novel Class I drug Olverembatinib (the determined English common name of HQP1351) of Guangzhou Healthquest Pharma Co., Ltd., a wholly-owned subsidiary of Ascentage Pharma, has obtained approval from the Center for Drug Evaluation (the "**CDE**") under the National Medical Products Administration of the People's Republic of China ("**NMPA**") that it has fulfilled the work procedure of the review and approval of new drugs with urgent clinical needs, and has been included in the list of "Priority Review". This commercialization application made in China is based on the results of two key phase II clinical studies, for the treatment of adult patients with acquired resistance to tyrosine kinase inhibitor (TKI) and T315I-mutant chronic phase chronic myeloid leukemia (CML) and accelerated phase CML.

According to NMPA's "Administrative Measures for Drug Registration" (No. 27 of the State Administration for Market Regulation) implemented on July 1, 2020 and the "Working Procedures for Priority Approval and Evaluation of Drug Marketing Authorization (Trial version)" (No. 82 of 2020) implemented on July 7, 2020, the approval department will prioritize the review and evaluation of drugs that have obtained priority review qualifications, so as to shorten the review and approval time and help speed up market entry through the initiation of a priority review and evaluation system to accelerate the development of new drugs with significant clinical value and urgent clinical needs. Olverembatinib was included as a priority review drug, which means that its approval is expected to be accelerated. If the application is approved, HQP1351 is expected to become the first third-generation BCR-ABL inhibitor to be marketed in China.

CML is a hematologic malignancy of the white blood cells. Despite significant clinical benefits offered by the first-and second-generation BCR-ABL inhibitors, acquired resistance to these drugs remains a major challenge in the treatment of CML, among which T315I mutation is one of the most common drug-resistant mutation. Hence, there is an urgent unmet clinical need for a new generation of effective treatment of CML.

Olverembatinib is a novel Class 1 drug under the research of the Ascentage Pharma, it is an orally active, potent third-generation BCR-ABL inhibitor designed to effectively target multi BCR-ABL mutants, including T315I. In July 2019, HQP1351 obtained clearance from the U.S. Food and Drug Administration (the "**US FDA**") to enter into Phase Ib clinical study. In May 2020, HQP1351 was granted Orphan Drug Designation and Fast Track Designation by the US FDA.

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 (HQP1351) successfully.

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

Suzhou, People's Republic of China, October 21, 2020

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, Mr. Zhao Qun, Dr. Lu Simon Dazhong and Mr. Liu Qian as non-executive Directors, and Mr. Ye Changqing, Dr. Yin Zheng and Mr. Ren Wei as independent non-executive Directors.