ASCENTAGE PHARMA GROUP INTERNATIONAL
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 6855)

Voluntary Announcement

Submission of New Drug Application for HQP1351 in China

Ascentage Pharma Group International (the “Company” or “Ascentage Pharma”) is pleased to announce that Guangzhou Healthquest Pharma Co., Ltd., a wholly-owned subsidiary of Ascentage Pharma, has submitted a New Drug Application (NDA) to the Center for Drug Evaluation (CDE) of China National Medical Products Administration (NMPA) for HQP1351, for the treatment of patients with T315I-mutant chronic phase chronic myeloid leukemia (CML) and accelerated phase CML. If the application is approved, HQP1351 is in the hopes of becoming the first marketed third-generation BCR-ABL inhibitor in China.

The Company recently engaged in pre-NDA discussions with the CDE regarding the NDA based on results from two pivotal registered clinical studies. The CDE has agreed that the Company shall proceed to submit the NDA for the two indications.

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 the most common drug-resistant mutation. Hence, there is an urgent unmet clinical need for the effective treatment of CML.

HQP1351 is a novel Class 1 drug under the research of the Company, 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 HQP1351 successfully.

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

Suzhou, People’s Republic of China, June 18, 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.