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ASCENTAGE PHARMA GROUP INTERNATIONAL

亞盛醫藥集團

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 6855)

Voluntary Announcement

HQP1351 Granted Fast Track Designation by the US FDA

Ascentage Pharma Group International (the “**Company**” or “**Ascentage Pharma**”) is pleased to announce that the US Food and Drug Administration (FDA) has granted HQP1351, the Company’s core drug candidate, a Fast Track Designation (FTD) for the treatment of chronic myeloid leukemia (CML) with certain genetic markers who have failed to respond to treatments with existing tyrosine kinase inhibitors (TKIs). This is the first FTD obtained by Ascentage Pharma.

The FDA’s Fast Track Designation is designed to facilitate the development and expedite the review of drug candidates to treat serious disease conditions that present an urgent unmet clinical need. CML is a hematologic malignancy, and marketed BCR-ABL tyrosine kinase inhibitors (TKIs) have significantly improved clinical management of CML. However, acquired resistance to TKIs remains a major challenge for CML treatment. HQP1351 is a novel, orally active, potent third-generation BCR-ABL inhibitor, developed for treatment of patients with CML resistant to first-and second-generation TKIs. HQP1351 was approved to enter a Phase Ib study in the US in July 2019 and was granted orphan drug designation recently by the US FDA.

HQP1351 is also the first third-generation BCR-ABL inhibitor targeting drug-resistant CML in China, and is currently in a pivotal Phase II study. The Company plans to submit an NDA for HQP1351 in China this year. The data from the Phase I clinical study of HQP1351 were selected for oral presentations at the American Society of Hematology (ASH) Annual Meetings 2 years in a row and was a nominated for “Best of ASH” research in 2019.

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, May 7, 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.