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

Positive Data from Pivotal Phase II Studies of HQP1351 (Olverembatinib) was announced at 2020 American Society of Hematology Annual Meeting

Ascentage Pharma Group International (the "**Company**" or "**Ascentage Pharma**") is pleased to announce positive data from two pivotal Phase II clinical trials studies of HQP1351 (Olverembatinib) was announced by way of oral presentation at the 62nd American Society of Hematology (ASH) Annual Meeting and the data was encouraging. These results were presented by the principal investigator of such studies, Professor Qian Jiang, MD, Deputy Chief of the Hematology Department at Peking University People's Hospital. Following our oral presentations in 2018 and 2019, this is the third consecutive time in which clinical progress of HQP1351 was selected for oral presentation at the ASH Annual Meetings, signifying the recognition of HQP1351's safety and efficacy from the international hematology community.

Highlights of the presentation:

- Two pivotal Phase II trials of HQP1351 in patients with TKI-resistant and T315I-mutated CML-CP or CML-AP were conducted in China. Patients in the studies were administered HQP1351 at 40 mg once every other day (QOD).

- As of the data cut-off date of March 23, 2020, pivotal Phase II study HQP1351-CC201 had enrolled 41 patients with CML-CP. Across a median follow-up of 7.9 months, the mean 3-month progression-free survival (PFS) was 100%, and the 6-month PFS was 96.7%. A total of 75.6% of evaluable patients achieved a major cytogenetic response (MCyR), including 65.9% with a complete cytogenetic response (CCyR) and 48.8% with a major molecular response (MMR).

- As of the data cut-off date of February 11, 2020, pivotal Phase II study HQP1351-CC202 had enrolled 23 patients with CML-AP. Across a median follow-up of 8.2 months, the 3-month PFS was 100% and the 6-month PFS was 95.5%. A total of 78.3% of evaluable patients achieved a major hematologic response (MaHR), including 60.9% of patients with a complete hematologic response (CHR). A further 52.2% of patients achieved MCyR, including 39.1% with CCyR and 26.1% with MMR.

- In study HQP1351-CC201, the most frequent treatment-related adverse event (TRAE) of Grade 3-4 was thrombocytopenia (48.8%), and there were no treatment-related deaths.

- In study HQP1351-CC202, the most frequent TRAE of Grade 3-4 was also thrombocytopenia (52.2%).

- Results from the two studies show that HQP1351 was efficacious and well tolerated in patients with T315I-mutated and TKI-resistant CML-AP or CML-CP, and the probability and depth of clinical response is expected to increase with prolonged treatment period.

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 (Olverembatinib) successfully.

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

Suzhou, People's Republic of China, December 8, 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.