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 APPROVED BY NMPA FOR TREATMENT OF CML-CP PATIENTS WHO ARE RESISTANT AND/OR INTOLERANT TO 1st AND 2nd GENERATION TKI TREATMENT

Ascentage Pharma Group International (the "**Company**" or "**Ascentage Pharma**") is pleased to announce that the Company's Class 1 innovative drug olverembatinib has been approved by the China National Medical Products Administration ("**NMPA**") for the treatment of adult patients with chronic-phase chronic myeloid leukemia (CML-CP) who are resistant and/or intolerant to 1st and 2nd generation tyrosine kinase inhibitors (TKIs). This approval represents another important milestone of the drug after it was first approved in 2021 and successfully included into the 2022 National Reimbursement Drug List, which will benefit a broader population of CML patients in China.

This approval is based on the results of an open-label, national multicenter, randomized controlled pivotal registrational Phase II clinical study (HQP1351CC203). The study was designed to evaluate the efficacy and safety of olverembatinib in patients with CML-CP who were resistant and/or intolerant to 1st and 2nd generation TKIs, who were randomly assigned to the olverembatinib treatment group and the Best Available Treatment (BAT) control group. Clinical data showed that patients receiving olverembatinib showed a statistically significant improvement compared to patients receiving BAT in the control group, meeting the primary endpoint of event-free survival (EFS).

CML is a hematological malignancy associated with white blood cells. The introduction of BCR-ABL TKIs has significantly improved the management of CML. However, 20% to 40% of patients still fail to achieve desired treatment outcome due to drug resistance or intolerance to TKI[1-3], eventually leading to disease progression or even death. Today, TKI resistance has become a global challenge for the treatment of CML, and there is an urgent clinical need for safe and effective new generation of drugs.

Olverembatinib is Ascentage Pharma's Class 1 innovative drug, which has received support from National Major New Drug Discovery and Manufacturing Program, and a best-in-class innovative drug globally. As the first and only marketed third generation BCR-ABL inhibitor, olverembatinib has outstanding effects on BCR-ABL and a variety of BCR-ABL mutants (including T315I mutation). In November 2021, olverembatinib was approved in China for the treatment of adult patients with TKI-resistant CML-CP or accelerated-phase CML (CML-AP) harboring the T315I mutation. In January 2023, olverembatinib has been officially included into the China National Reimbursement Drug List, further bolstering the affordability and accessibility of the drug. The commercialization of the drug in China is jointly undertaken by Ascentage Pharma and Innovent Biologics, Inc.

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

Suzhou, People's Republic of China, November 17, 2023

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 and Dr. Lu Simon Dazhong as non-executive Directors, and Mr. Ye Changqing, Dr. Yin Zheng, Mr. Ren Wei and Dr. David Sidransky as independent non-executive Directors.

References:

1. O'Brien SG, Guilhot F, Larson R, et al. Imatinib compared with interferon and low-dose cytarabine for newly diagnosed chronic-phase chronic myeloid leukemia. *Engl J Med*. 2003 Mar 13;348(11):994-1004.

2. Jabbour E, Kantarjian H. Chronic myeloid leukemia: 2014 update on diagnosis, monitoring, and management. *Am J Hematol*. 2014 May;89(5):547-56.

3. Larson R, Hochhaus A, Hughes T, et al. Nilotinib vs imatinib in patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase: ENESTnd 3-year follow-up. *Leukemia*. 2012 Oct;26(10):2197-203.