ASCENTAGE PHARMA GROUP INTERNATIONAL

亞盛醫藥集團

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 6855)

Voluntary Announcement

Ascentage Pharma Announces CDE's Approval for the Phase III Pivotal Study in China of Olverembatinib for the Treatment of Philadelphia Chromosome-positive Acute Lymphoblastic Leukemia (Ph+ ALL)

Ascentage Pharma Group International (the "**Company**" or "**Ascentage Pharma**") is pleased to announce that the Center for Drug Evaluation (CDE) of China National Medical Products Administration (NMPA) has approved the Phase III pivotal study of olverembatinib, one of the core drugs of the Company, in combination with chemotherapy versus imatinib in combination with chemotherapy in patients with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL), which may potentially make olverembatinib the first TKI for the first-line treatment of Ph+ ALL in China.

Ph+ ALL, which accounts for approximately 20%-30% of adult ALL patients, has the characteristics of high recurrence rate, short disease-free survival and poor prognosis. Before the advent of small molecule targeted tyrosine kinase inhibitors (TKIs), allogeneic hematopoietic stem cell transplantation (allo-HSCT) after achieving complete response (CR) through chemotherapy was considered as the first-line treatment for patients with Ph+ ALL. However, 70% of patients recurred before transplantation or were lack of transplantation opportunities, and the 5-year overall survival rate (OS) was less than 30%[1]. The application of TKIs has significantly changed the treatment prospect of Ph+ ALL, but there are certain limitations in the treatment of first-generation and second-generation TKIs. The recurrence rate and the long-term survival rate are still unsatisfactory with the 3-5 years OS at about 50%[2]. This is mainly related to the relatively low complete molecular response rate (CMR) and T315I kinase domain mutation. Therefore, there is considerable room for improvement in the treatment of Ph+ ALL. At present, no TKI has been approved for the first-line treatment of patients with Ph+ ALL in China.

Olverembatinib is a type 1 novel drug developed by Ascentage Pharma, an oral third-generation TKI, and the first and only third-generation BCR-ABL inhibitor approved for marketing in China. Ascentage Pharma and Innovent Biologics, Inc. are jointly responsible for the commercialization of olverembatinib in China. Its indication for the treatment of adult patients with TKI-resistant chronic myeloid leukemia (CML) in chronic phase (-CP) or accelerated phase (-AP) with T315I mutation has been approved by the Center for Drug Evaluation (CDE) of NMPA for marketing in November 2021. Previously, the drug was recommended by the CSCO Guidelines for Hematological Malignancies for the treatment of patients with Ph+ ALL.

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

Suzhou, People's Republic of China, July 4, 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. Fielding A K, Rowe JM, Richards SM, et a1. Prospective outcome data on 267 unselected adult patients with Philadelphia chromosome positive acute lymphoblastic leukemia confirms superiority of allogeneic transplantation over chemotherapy in the pre imatinib era results from the International ALL Trim MRCUKALIXII/ECOG 2993. Blood, 2009,113: 4489 – 4496.

2. Elias Jabbour et. Treatment of Adults With Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia-From Intensive Chemotherapy Combinations to Chemotherapy-Free Regimens: A Review. JAMA Oncol. 2022 Sep 1;8(9):1340-1348.