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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

Ascentage Pharma Announces Global Registrational Phase III Study of Olverembatinib in First-Line Treatment of Ph+ ALL Cleared by US FDA and EMA

Ascentage Pharma Group International (the “**Company**” or “**Ascentage Pharma**”) is pleased to announce that it has received clearance from the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to conduct a global registrational Phase III study (POLARIS-1; NCT06051409) of its compound under investigation, olverembatinib, in combination with chemotherapy for the treatment of newly diagnosed patients with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL). As the second global registrational Phase III study of olverembatinib that has been cleared by regulators in the US and Europe, the POLARIS-1 study is simultaneously enrolling patients across trial centers in multiple countries in order to accelerate olverembatinib’s path to registration worldwide, particularly in the US and European markets.

The POLARIS-1 trial is a global, multicenter, randomized controlled, open-label Phase III study designed to evaluate the efficacy and safety of olverembatinib in combination with chemotherapy in newly diagnosed patients with Ph+ ALL. The POLARIS-1 study was also initiated in China after it was cleared by the China Center for Drug Evaluation (CDE) in 2023.

The POLARIS-1 study is set to release its first dataset at the upcoming 2025 American Society of Hematology (ASH) Annual Meeting. Data disclosed in the ASH 2025 abstract showed that among treatment-naïve patients with Ph+ ALL who received olverembatinib in combination with low-intensity chemotherapy, the minimal residual disease (MRD) negativity rate and the molecular MRD-negative complete response (CR) rate at the end of three treatment cycles both reached approximately 65%, which significantly improved the efficacy reported for other drugs in the same class. Notably, the combination regimen also demonstrated favorable clinical benefit in patients with certain high-risk subtypes such as those harboring the IKZF1^{plus} mutation. In addition, the combination regimen demonstrated a favorable safety profile, with a low incidence of adverse events which were mostly manageable.

Accounting for 20%-30% of all ALL cases in adults, Ph+ ALL is commonly associated with a disproportionately high incidence in the elderly population, a high relapse rate, short disease-free survival, and poor prognosis. Prior to the introduction of tyrosine kinase inhibitors (TKIs), chemotherapy-only treatment delivered a five-year overall survival (OS) rate of less than 20%. The clinical adoption of TKIs has resulted in a new clinical paradigm for patients with Ph+ ALL. However, first- and second-generation TKIs have considerable limitations in the treatment of Ph+ ALL.

Developed by Ascentage Pharma, olverembatinib is an orally administered, third-generation TKI and the first China-approved third-generation BCR-ABL inhibitor, currently being jointly commercialized in China by Ascentage Pharma and Innovent Biologics, Inc. Olverembatinib has already been approved in China in multiple indications in drug-resistant chronic myeloid leukemia (CML) and all of the approved indications are now covered by the China National Reimbursement Drug List (NRDL). Being developed for the treatment of Ph+ ALL, olverembatinib has received consecutive recommendations in the Chinese Society of Clinical Oncology (CSCO) Guidelines for the Diagnosis and Treatment of Hematologic Malignancies and a Breakthrough Therapy Designation by the China CDE.

On June 14, 2024, Ascentage signed an exclusive option agreement to enter into an exclusive license agreement with Takeda for olverembatinib. In the event that Takeda exercises the option, Takeda would license the global rights to develop and commercialize olverembatinib in all territories outside of, among others, mainland China, Hong Kong, Macau, and Taiwan, China.

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

Suzhou, People's Republic of China, December 5, 2025

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^{Note}, and Mr. Ye Changqing, Mr. Ren Wei and Dr. David Sidransky and Ms. Marina S. Bozilenko and Dr. Debra Yu and Marc E. Lippman, MD as independent non-executive Directors.

Note: Dr. Wang Shaomeng and Dr. Lu Simon Dazhong are independent directors under NASDAQ rules.