
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934

For the month of **December 2025**

Commission File Number: **001-42484**

ASCENTAGE PHARMA GROUP INTERNATIONAL
(Translation of Registrant's name into English)

68 Xinqing Road
Suzhou Industrial Park
Suzhou, Jiangsu
China

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

EXPLANATORY NOTE

On December 8, 2025, Ascentage Pharma Group International issued three press releases entitled (1) “ASH 2025 | Updated Data for Ascentage Pharma’s Olverembatinib in Second-Line CML-CP Showing Encouraging Potential for Early-Line Treatment”, (2) “ASH 2025 | Ascentage Pharma Presents First Dataset from Phase III POLARIS-1 Study of Olverembatinib in Newly Diagnosed Ph+ ALL Shows a Best MRD-Negativity CR Rate Exceeding 60%” and (3) “ASH 2025 | Ascentage Pharma Presents Four-Year Follow-Up Data from Registrational Phase II Study of Olverembatinib, Reaffirming Differentiated Long-Term Efficacy and Safety in TKI-Resistant/Intolerant CML-CP”. A copy of each press release is furnished as Exhibits 99.1, 99.2 and 99.3 to this Report.

INDEX TO EXHIBITS

Exhibit Number	Exhibit Title
99.1	Press Release dated December 8, 2025
99.2	Press Release dated December 8, 2025
99.3	Press Release dated December 8, 2025

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ASCENTAGE PHARMA GROUP INTERNATIONAL

Date: December 9, 2025

/s/ Dajun Yang

Name: Dajun Yang

Title: Chief Executive Officer



ASH 2025 | Updated Data for Ascentage Pharma's Olverembatinib in Second-Line CML-CP Showing Encouraging Potential for Early-Line Treatment

- *76.7% complete cytogenetic response rate achieved in patients who failed second-generation TKI first-line therapy*
- *Molecular responses continue to deepen with extended treatment duration, reaching 60% major molecular response at 21 cycles*
- *Strong efficacy data support potential advancement to earlier treatment lines for a broader patient population*

ROCKVILLE, Md. and SUZHOU, China, December 8, 2025—Ascentage Pharma Group International (NASDAQ: AAPG; HKEX: 6855), a global, commercial-stage, integrated biopharmaceutical company engaged in the discovery, development, and commercialization of novel, differentiated therapies to address unmet medical needs in cancer, announced that it has presented the latest data on Olverembatinib, the Company's novel drug, in second-line treatment of patients with chronic myeloid leukemia (CML) in chronic-phase (-CP), in a poster presentation at the 67th American Society of Hematology (ASH) Annual Meeting, being held in Orlando, Florida. This presentation provided an update on the results released in an oral presentation at ASH 2024 and featured data from a longer follow-up on efficacy and safety.

The ASH Annual Meeting is one of the largest gatherings of the international hematology community, aggregating cutting-edge scientific research and the latest data on investigational therapies that represent leading scientific and clinical advances in the global hematology field. Once again, Ascentage Pharma's innovative pipeline has garnered significant attention at this year's conference, with results from multiple clinical and preclinical studies on three of the company's drug candidates (Olverembatinib, Lixaftoclax, and APG-5918) selected for presentations, including an oral report.

The updated results suggest that Olverembatinib holds promise as a safe and effective new treatment option for patients with second-line CML-CP, especially those who failed first- and second-generation BCR-ABL1 tyrosine kinase inhibitors (TKIs). As of the data cut-off date, in patients with CP-CML resistant/intolerant to one prior line of TKIs without the T315I mutation, Olverembatinib demonstrated a complete cytogenetic response (CCyR) rate and a major molecular response (MMR) rate of 71.8% and 43.6%. In patients who failed first-line treatment with second-generation TKIs, Olverembatinib demonstrated a CCyR rate of 76.7% and an MMR rate of 43.3%. Moreover, patients' responses deepened with time on treatment. Safety data presented in the poster were consistent with previously reported results, with no new safety signals.

Olverembatinib is a novel drug developed by Ascentage Pharma and represents the first third-generation BCR-ABL inhibitor approved in China. Olverembatinib is currently being jointly commercialized in China by Ascentage Pharma and Innovent Biologics. The drug is currently approved in China for adult patients with TKI-resistant chronic-phase chronic myeloid leukemia (CML-CP) or accelerated-phase CML (CML-AP) harboring the T315I mutation; and adult patients with CML-CP resistant to and/or intolerant of first- and second-generation TKIs, with all approved indications now covered by the China National Reimbursement Drug List (NRDL). Ascentage Pharma is currently conducting three global registrational Phase III studies to evaluate Olverembatinib, as an investigational drug, in multiple indications including CML-CP, newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph⁺ ALL), and succinate dehydrogenase (SDH)- deficient gastrointestinal stromal tumors (GIST). Ascentage Pharma has 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.

Professor Weiming Li, the presenter of this study, from the Union Hospital, Tongji Medical College, Huazhong University of Science and Technology in Wuhan, commented, “Since its first dataset was released in an oral presentation at last year’s ASH Annual Meeting, this study has attracted widespread interest from the international hematology community for the high response rates and favorable safety profile it observed in patients with second-line CML-CP. The updated data presented this year reaffirmed the previously reported favorable results, showing deepened responses with longer duration of treatment. The study has yielded strong evidence supporting Olverembatinib’s therapeutic utility for second-line treatment of CML-CP, paving the way for broader clinical application of Olverembatinib.”

Yifan Zhai, M.D., Ph.D., Chief Medical Officer of Ascentage Pharma, said, “We are delighted that updated data from this study were presented once again at the ASH Annual Meeting. The latest data suggest that Olverembatinib has potential as a safe and effective new treatment option for a broader population of patients with CML-CP. Fulfilling our mission of addressing unmet clinical needs in China and around the world, we will strive to accelerate our clinical programs to bring more safe and effective therapies to patients as soon as possible.”

Highlights of the data this study reported at ASH 2025 are as below:

Updated efficacy and safety of olverembatinib (HQP1351) as second-line therapy in patients with chronic phase-chronic myeloid leukemia (CP-CML)

Format: Poster Presentation

Abstract#: 3782

Session: 632. Chronic Myeloid Leukemia: Clinical and Epidemiological: Poster II

Time: Sunday, December 7, 2025; 6:00 PM – 8:00 PM EST

First Author: Professor Weiming Li, Department of Hematology, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China

Presenter: Professor Weiming Li, Department of Hematology, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China

Highlights:

Background:

BCR-ABL1 TKIs have significantly improved the prognosis of patients with CML. However, some patients develop drug resistance or intolerance during treatment with TKIs. Prior studies showed that 20% to 30% of patients with CML who were treated with imatinib, and more than 10% of patients who received first-line treatment with second-generation TKIs dasatinib or nilotinib, developed drug resistance or intolerance in the first year. Therefore, Chinese patients with CML-CP resistant/intolerant to one prior line of TKIs have an urgent unmet medical need.

Introduction:

This was an open-label, single-arm, multicenter clinical study (ChiCTR2200061655) designed to evaluate the efficacy and safety of orally administered Olverembatinib at 40 mg every other day (QOD) in Chinese patients with CP-CML resistant/intolerant to one prior line of TKIs (including imatinib, flumatinib, nilotinib, and dasatinib) without the T315I mutation. As of July 24, 2025, the study had enrolled 47 patients with CP-CML without the T315I mutation.

Efficacy Results:

- As of July 24, 2025, 39 (83.0%) patients received at least one efficacy evaluation; 36 (76.6%) at least two efficacy evaluations; and 34 (72.3%) at least three efficacy evaluations. Two patients had not yet received their first efficacy evaluation.
- As of the data cut-off date, 71.8% (28/39) of patients had achieved a CCyR and 43.6% (17/39) MMR. CCyR and MMR rates assessed at the end of cycles 6, 9, 12, 15, 18, 21, and 24 were 54.3% and 25.7%, 66.7% and 33.3%, 74.2% and 35.5%, 84.6% and 46.2%, 85.7% and 47.6%, 90.0% and 60.0%, and 89.5% and 57.9%, respectively, suggesting that responses deepened as treatment persisted.
- Among 39 efficacy-evaluable patients, 30 had received second-generation TKIs in first-line treatment. Of them, 76.7% (23/30) achieved a CCyR and 43.3% (13/30) MMR. Among the 9 patients who were pretreated with imatinib, 55.6% (5/9) achieved a CCyR and 44.4% (4/9) MMR.

Safety Results: The median (range) treatment duration was 16.0 (1-18) cycles. A total of 42 (89.4%) patients experienced treatment-related adverse events (TRAEs) of any grade, including 21 (44.7%) patients who experienced grade ≥ 3 TRAEs and 6 (12.8%) patients who experienced serious adverse events (SAEs) related to Olverembatinib. Grade ≥ 3 hematologic toxicities included platelet count decreased (42.6%), neutrophil count decreased (25.5%), and anemia (8.5%). Olverembatinib-related SAEs included platelet count decreased (6.4%) and anemia, myelosuppression, and pyrexia (2.1% each). No deaths were reported during the study.

Conclusion: Olverembatinib may provide a safe and effective second-line treatment for patients with CP-CML, especially for those with disease that had failed on first-line treatment with second-generation TKIs.

** Olverembatinib, Lisafoclax, and APG-5918 are currently under investigation and have not been approved by the US FDA.*

About Ascentage Pharma

Ascentage Pharma Group International (NASDAQ: AAPG; HKEX: 6855) (“Ascentage Pharma” or the “Company”) is a global, commercial stage, integrated biopharmaceutical company engaged in the discovery, development and commercialization of novel, differentiated therapies to address unmet medical needs in cancer. The Company has built a rich pipeline of innovative drug products and candidates that includes inhibitors targeting key proteins in the apoptotic pathway, such as Bcl-2 and MDM2-p53, as well as next-generation kinase inhibitors.

The lead asset, Olverembatinib, is the first novel third-generation BCR-ABL1 inhibitor approved in China for the treatment of patients with CML in chronic phase (CML-CP) with T315I mutations, CML in accelerated phase (CML-AP) with T315I mutations, and CML-CP that is resistant or intolerant to first and second-generation TKIs. All indications are covered by the China National Reimbursement Drug List (NRDL). The Company is currently conducting an FDA-cleared, global registrational Phase III trial, or POLARIS-2, of Olverembatinib for CML, as well as global registrational Phase III trials for patients with newly diagnosed Ph+ ALL and SDH-deficient GIST patients.

The Company’s second approved product, Lisafoclax, is a novel Bcl-2 inhibitor for the treatment of various hematologic malignancies. Lisafoclax is being commercialized in China following National Medical Products Administration (NMPA) approval for the treatment of adult patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) who have previously received at least one systemic therapy including Bruton’s tyrosine kinase (BTK) inhibitors. The Company is currently conducting four global registrational Phase III trials: the FDA-cleared GLORA study of Lisafoclax in combination with BTK inhibitors in patients with CLL/SLL previously treated with BTK inhibitors for more than 12 months with suboptimal response; the GLORA-2 study in patients with newly diagnosed CLL/SLL; the GLORA-3 study in newly diagnosed, elderly and unfit patients with acute myeloid leukemia (AML); and the GLORA-4 study in patients with newly diagnosed higher-risk myelodysplastic syndrome (HR MDS), a study that was simultaneously cleared by the U.S. FDA, the EMA of the EU, and China CDE.

Leveraging its robust R&D capabilities, Ascentage Pharma has built a portfolio of global intellectual property rights and entered into global partnerships and other relationships with numerous leading biotechnology and pharmaceutical companies, such as Takeda, AstraZeneca, Merck, Pfizer, and Innovent, in addition to research and development relationships with leading research institutions, such as Dana-Farber Cancer Institute, Mayo Clinic, National Cancer Institute and the University of Michigan. For more information, visit <https://ascentage.com/>

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical facts, contained in this press release may be forward-looking statements, including statements that express Ascentage Pharma's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results of operations or financial condition.

These forward-looking statements are subject to a number of risks and uncertainties as discussed in Ascentage Pharma's filings with the SEC, including those set forth in the sections titled "Risk factors" and "Special note regarding forward-looking statements and industry data" in its Registration Statement on Form F-1, as amended, filed with the SEC on January 21, 2025, and the Form 20-F filed with the SEC on April 16, 2025, the sections headed "Forward-looking Statements" and "Risk Factors" in the prospectus of the Company for its Hong Kong initial public offering dated October 16, 2019, and other filings with the SEC and/or The Stock Exchange of Hong Kong Limited we made or make from time to time that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements contained in this presentation do not constitute profit forecast by the Company's management.

As a result of these factors, you should not rely on these forward-looking statements as predictions of future events. The forward-looking statements contained in this press release are based on Ascentage Pharma's current expectations and beliefs concerning future developments and their potential effects and speak only as of the date of such statements. Ascentage Pharma does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.



ASH 2025 | Ascentage Pharma Presents Four-Year Follow-Up Data from Registrational Phase II Study of Olverembatinib, Reaffirming Differentiated Long-Term Efficacy and Safety in TKI-Resistant/Intolerant CML-CP

- *Dramatically improved disease control with 21.2 months vs. 2.9 months median event-free survival (EFS)*
- *Favorable safety profile with 7% vascular occlusion rate*
- *Broad patient benefit with proven effectiveness even in patients without T315I mutation (11.9 vs. 3.1 months event-free survival)*

ROCKVILLE, Md. and SUZHOU, China, December 8, 2025—Ascentage Pharma Group International (NASDAQ: AAPG; HKEX: 6855), a global, commercial stage, integrated biopharmaceutical company engaged in the discovery, development and commercialization of novel, differentiated therapies to address unmet medical needs in cancer, announced that it presented four year follow-up data from its randomized controlled, registrational Phase II study of Olverembatinib in patients with tyrosine kinase inhibitor (TKI)-resistant/intolerant chronic-phase chronic myeloid leukemia (CML-CP), in a poster presentation at the 67th American Society of Hematology (ASH) Annual Meeting, being held in Orlando, Florida. Building on results released in an oral presentation at ASH 2023, these data reaffirm Olverembatinib's differentiated long-term efficacy and safety.

The ASH Annual Meeting is one of the largest gatherings of the international hematology community, aggregating cutting-edge scientific research and the latest data on investigational therapies that represent leading scientific and clinical advances in the global hematology field. Once again, Ascentage Pharma's innovative pipeline has garnered significant attention at this year's conference, with results from multiple clinical and preclinical studies on three of the Company's investigational drug candidates (Olverembatinib, Lisaftoclax, and APG-5918) selected for presentations, including an oral report.

In the four year follow-up data, Olverembatinib consistently demonstrated a clear efficacy advantage over investigator's choice of current best available therapy (BAT) (in China) for patients with TKI-resistant/intolerant CML-CP (including those without the T315I mutation). Among all patients with CML-CP, the Olverembatinib arm demonstrated a median event-free survival (EFS) of 21.2 months, which was significantly longer than the 2.9 months observed in the BAT arm. Among patients with CML-CP without the T315I mutation, the Olverembatinib arm demonstrated an EFS of 11.9 months, which was also significantly longer than the 3.1 months observed in the BAT arm. Notably, the long-term follow-up data showed a favorable safety profile, with vascular occlusion reported by 7% of patients.

Olverembatinib is a novel drug developed by Ascentage Pharma and represents the first third-generation BCR-ABL1 inhibitor approved in China. Olverembatinib is currently being jointly commercialized in China by Ascentage Pharma and Innovent Biologics. The drug is currently approved in China for: adult patients with TKI-resistant chronic-phase chronic myeloid leukemia (CML-CP) or accelerated-phase CML (CML-AP) harboring the T315I mutation; and adult patients with CML-CP resistant to and/or intolerant of first- and second-generation TKIs, with all approved indications now covered by the China National Reimbursement Drug List (NRDL). Ascentage Pharma is currently conducting three global registrational Phase III studies to evaluate Olverembatinib in multiple indications, including CML-CP, newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL), and succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumors (GIST). Ascentage Pharma has 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.

Professor Qian Jiang, presenter of this study from Peking University Institute of Hematology, Peking University People's Hospital, commented, "The latest data from this registrational Phase II study reaffirm the excellent efficacy and long-term safety of Olverembatinib in patients with TKI-resistant/intolerant CML-CP, including those without the T315I mutation. Notably, the incidence rate of vascular occlusion was 7%. These findings give physicians and patients the crucial confidence needed for long-term treatment, reinforcing the drug's established role in clinical practice."

Yifan Zhai, M.D., Ph.D., Chief Medical Officer of Ascentage Pharma, said, "After a four year follow-up, this pivotal study continued to mature with additional encouraging data. While affirming the drug's durable efficacy, it also demonstrated an excellent long-term safety profile, which will contribute to patients' quality of life and enable them to benefit from long-term treatment. Fulfilling our mission of addressing unmet clinical needs in China and around the world, we will strive to accelerate our clinical programs to bring more safe and effective therapies to patients as soon as possible."

Highlights of the data this study reported at ASH 2025 are as below:

Olverembatinib (HQP1351) demonstrates efficacy vs. best available therapy (BAT) in patients (pts) with tyrosine kinase inhibitor (TKI)-resistant chronic-phase chronic myeloid leukemia (CML-CP) in a registrational randomized phase 2 trial: up to 4-year follow-up including patients without T315I mutations

Format: Poster Presentation

Abstract#: 3788

Session: 632. Chronic Myeloid Leukemia: Clinical and Epidemiological: Poster II

Time: Sunday, December 7, 2025; 06:00 PM - 08:00 PM EST

First Author: Professor Qian Jiang, M.D., Peking University Institute of Hematology, Peking University People's Hospital, Beijing, China

Presenter: Professor Qian Jiang, M.D., Peking University Institute of Hematology, Peking University People's Hospital, Beijing, China

Highlights:

Background:

CML is an acquired malignant clonal disease of hematopoietic stem cells. The introduction of TKIs has transformed the natural history of CML, normalizing life expectancy for many patients. However, a considerable proportion of patients eventually discontinue treatment because of acquired drug resistance or intolerance. Therefore, many patients with CML resistant to or intolerant of first- and second-generation TKIs lack effective treatment options and may face a higher risk of disease progression. Olverembatinib is a potent third-generation BCR-ABL1 TKI with strong efficacy and favorable safety in patients with CML who harbor the wild-type or T315I-mutant *BCR::ABL1*; the latter confers resistance against imatinib and second-generation TKIs.

Introduction:

- This was an open-label, randomized controlled, multicenter, pivotal registrational Phase II study (NCT04126681) designed to evaluate the efficacy and safety of olverembatinib in patients with CML-CP resistant and/or intolerant to first- and second-generation TKIs. This report features an update on results released in an oral presentation at ASH 2023. As of January 13, 2025, a total of 144 patients with CML-CP were enrolled in the study, including 105 patients without the T315I mutation.
- In this study, patients were randomized in a 2:1 ratio to the olverembatinib arm or the control arm with investigators' choices of best available treatment (BAT).
- The primary endpoint was event-free survival (EFS). An event was defined as disease progression; loss of achieved complete hematologic response (CHR), major cytogenetic response, or complete cytogenetic response (CCyR); treatment failure; no achieved CHR within 3 cycles; death from any cause; or unacceptable toxicity.

Efficacy Results:

- The olverembatinib arm achieved a significantly longer EFS than the BAT arm: among all patients with CML-CP, the median EFS of the olverembatinib arm and the BAT arm were 21.2 months and 2.9 months ($P < 0.0001$), respectively. Among patients with CML-CP without the T315I mutation, the median EFS of the olverembatinib arm and the BAT arm were 11.9 months and 3.1 months ($P = 0.0159$), respectively.
- Other efficacy parameters of the olverembatinib arm were significantly better than those of the BAT arm: among all patients with CML-CP, CHR rates of the olverembatinib arm and the BAT arm were 85% and 35%; CCyR rates were 38% and 19%; and major molecular response (MMR) rates were 30% and 8%, respectively. Among patients with CML-CP without the T315I mutation treated in the olverembatinib arm or the BAT arm, CHR rates were 82% and 50%, CCyR rates 26% and 21%, and MMR rates 16% and 10%, respectively.

Safety Results: Olverembatinib showed a favorable safety profile in patients with CML-CP with/without the T315I mutation, with no new safety signals. Grade ≥ 3 adverse events included hematologic toxicities. Notably, the incidence rate of vascular occlusion in the olverembatinib arm was 7%.

Conclusion: Olverembatinib demonstrated a clear therapeutic advantage over BAT in patients with CML-CP resistant and/or intolerant to first- and second-generation TKIs, including those without the T315I mutation.

** Olverembatinib, Lisoftoclax and APG-5918 are currently under investigation and have not yet been approved by the FDA in the U.S.*

About Ascentage Pharma

Ascentage Pharma Group International (NASDAQ: AAPG; HKEX: 6855) (“Ascentage Pharma” or the “Company”) is a global, commercial stage, integrated biopharmaceutical company engaged in the discovery, development and commercialization of novel, differentiated therapies to address unmet medical needs in cancer. The Company has built a rich pipeline of innovative drug products and candidates that includes inhibitors targeting key proteins in the apoptotic pathway, such as Bcl-2 and MDM2-p53, as well as next-generation kinase inhibitors.

The lead asset, Olverembatinib, is the first novel third-generation BCR-ABL1 inhibitor approved in China for the treatment of patients with CML in chronic phase (CML-CP) with T315I mutations, CML in accelerated phase (CML-AP) with T315I mutations, and CML-CP that is resistant or intolerant to first and second-generation TKIs. All indications are covered by the China National Reimbursement Drug List (NRDL). The Company is currently conducting an FDA-cleared, global registrational Phase III trial, or POLARIS-2, of Olverembatinib for CML, as well as global registrational Phase III trials for patients with newly diagnosed Ph+ ALL and SDH-deficient GIST patients.

The Company’s second approved product, Lisoftoclax, is a novel Bcl-2 inhibitor for the treatment of various hematologic malignancies. Lisoftoclax is being commercialized in China following National Medical Products Administration (NMPA) approval for the treatment of adult patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) who have previously received at least one systemic therapy including Bruton’s tyrosine kinase (BTK) inhibitors. The Company is currently conducting four global registrational Phase III trials: the FDA-cleared GLORA study of Lisoftoclax in combination with BTK inhibitors in patients with CLL/SLL previously treated with BTK inhibitors for more than 12 months with suboptimal response; the GLORA-2 study in patients with newly diagnosed CLL/SLL; the GLORA-3 study in newly diagnosed, elderly and unfit patients with acute myeloid leukemia (AML); and the GLORA-4 study in patients with newly diagnosed higher-risk myelodysplastic syndrome (HR MDS), a study that was simultaneously cleared by the U.S. FDA, the EMA of the EU, and China CDE.

Leveraging its robust R&D capabilities, Ascentage Pharma has built a portfolio of global intellectual property rights and entered into global partnerships and other relationships with numerous leading biotechnology and pharmaceutical companies, such as Takeda, AstraZeneca, Merck, Pfizer, and Innovent, in addition to research and development relationships with leading research institutions, such as Dana-Farber Cancer Institute, Mayo Clinic, National Cancer Institute and the University of Michigan. For more information, visit <https://ascentage.com/>

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical facts, contained in this press release may be forward-looking statements, including statements that express Ascentage Pharma's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results of operations or financial condition.

These forward-looking statements are subject to a number of risks and uncertainties as discussed in Ascentage Pharma's filings with the SEC, including those set forth in the sections titled "Risk factors" and "Special note regarding forward-looking statements and industry data" in its Registration Statement on Form F-1, as amended, filed with the SEC on January 21, 2025, and the Form 20-F filed with the SEC on April 16, 2025, the sections headed "Forward-looking Statements" and "Risk Factors" in the prospectus of the Company for its Hong Kong initial public offering dated October 16, 2019, and other filings with the SEC and/or The Stock Exchange of Hong Kong Limited we made or make from time to time that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements contained in this presentation do not constitute profit forecast by the Company's management.

As a result of these factors, you should not rely on these forward-looking statements as predictions of future events. The forward-looking statements contained in this press release are based on Ascentage Pharma's current expectations and beliefs concerning future developments and their potential effects and speak only as of the date of such statements. Ascentage Pharma does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.



ASH 2025 | Ascentage Pharma Presents First Dataset from Phase III POLARIS-1 Study of Olverembatinib in Newly Diagnosed Ph+ ALL Shows a Best MRD-Negativity CR Rate Exceeding 60%

- *By the end of 3 induction cycles, the best minimal residual disease (MRD) negativity rate and the MRD-negative complete response (CR) rate were 66.0% and 64.2%, respectively*
- *High-risk IKZF1^{plus} patients showed 90% molecular response rate*
- *Low-intensity chemotherapy combination achieved deep responses with favorable safety profile*

ROCKVILLE, Md. and SUZHOU, China, December 8, 2025—Ascentage Pharma Group International (NASDAQ: AAPG; HKEX: 6855), a global, commercial-stage, integrated biopharmaceutical company engaged in the discovery, development, and commercialization of novel, differentiated therapies to address unmet medical needs in cancer, announced that it has presented the first dataset from the global registrational Phase III study (POLARIS-1) of the company's novel, investigational drug, Olverembatinib (HQP1351), in combination with low-intensity chemotherapy in patients with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph⁺ ALL), in a poster presentation at the 67th American Society of Hematology (ASH) Annual Meeting, being held in Orlando, Florida.

The ASH Annual Meeting is one of the largest gatherings of the international hematology community, aggregating cutting-edge scientific research and the latest data on investigational therapies that represent leading scientific and clinical advances in the global hematology field. Once again, Ascentage Pharma's innovative pipeline has garnered significant attention at this year's conference. Results from multiple clinical and preclinical studies on three of Ascentage Pharma's investigational drug candidates (Olverembatinib, Lisaftoclax, and APG-5918) have been selected for presentation, including an oral report, at this year's ASH Annual Meeting.

This poster presentation on the registrational Phase III POLARIS-1 study highlighted the promising therapeutic potential of Olverembatinib in Ph⁺ ALL. The data showed that, for the treatment of newly diagnosed patients who received Olverembatinib in combination with low-intensity chemotherapy, the best minimal residual disease (MRD) negativity rate and the MRD-negative complete response (CR) rate by the end of 3 induction cycles were 66.0% and 64.2%, respectively, alongside a favorable safety profile.

Olverembatinib is a novel drug developed by Ascentage Pharma and represents the first third-generation BCR-ABL inhibitor approved in China. Olverembatinib is currently being jointly commercialized in China by Ascentage Pharma and Innovent Biologics. The drug is currently approved in China for: adult patients with tyrosine kinase inhibitor (TKI)-resistant chronic-phase chronic myeloid leukemia (CML-CP) or accelerated-phase CML (CML-AP) harboring the T315I mutation; and adult patients with CML-CP resistant to and/or intolerant of first- and second-generation TKIs, with all approved indications now covered by the China National Reimbursement Drug List (NRDL). Ascentage Pharma is currently conducting three global registrational Phase III studies to evaluate Olverembatinib in multiple indications, including CML-CP, Ph⁺ ALL, and succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumors. Notably, the POLARIS-1 study was recently cleared by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), marking another major milestone in the global development of olverembatinib. Ascentage Pharma has 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.

Professor Suning Chen, presenter of this study from the Department of Hematology, The First Affiliated Hospital of Soochow University, commented, “Olverembatinib is emerging as a cornerstone in investigational combination chemotherapy regimens for patients with Ph⁺ ALL. It achieved both deep responses and low toxicity and therefore having the potential to bring a long-awaited new treatment to this indication. At this year’s ASH Annual Meeting, we presented data from the first part of the POLARIS-1 study that showed deep MRD-negative responses in more than 60% of previously untreated patients with Ph⁺ ALL who received Olverembatinib in combination with low-intensity chemotherapy, at the end of three induction cycles . These encouraging results validate Olverembatinib’s global potential for reshaping the therapeutic landscape for Ph⁺ ALL.”

Yifan Zhai, M.D., Ph.D., Chief Medical Officer of Ascentage Pharma, said, “At ASH 2025, we presented the first dataset from the POLARIS-1 study that positioned Olverembatinib as a highly promising potential new treatment option for patients with Ph⁺ ALL. Supported by the favorable clinical benefit and tolerability that Olverembatinib demonstrated in Ph⁺ ALL, the POLARIS-1 trial was recently cleared by FDA and EMA. We are optimistic that Olverembatinib-based innovative regimens will bring a new paradigm to the treatment of Ph⁺ ALL. Fulfilling our mission of addressing unmet clinical needs in China and around the world, we will strive to accelerate our clinical programs to bring more safe and effective therapies to patients as soon as possible.”

Highlights of the data this study reported at ASH 2025 are as below:

Results of POLARIS-1, a global phase 3 study (Part A): olverembatinib combined with low-intensity chemotherapy in patients with newly diagnosed (ND) Philadelphia chromosome-positive (Ph⁺) acute lymphoblastic leukemia (ALL)

Format: Poster Presentation

Abstract#: 1574

Session: 613. Acute Lymphoblastic Leukemias: Therapies Excluding Allogeneic Transplantation: Poster I

Time: Saturday, December 6, 2025; 5:30 PM – 7:30 PM EST

First Author: Professor Suning Chen, Ph.D. Department of Hematology, The First Affiliated Hospital of Soochow University, Suzhou, China

Presenter: Professor Suning Chen, Ph.D., Department of Hematology, The First Affiliated Hospital of Soochow University, Suzhou, China

Highlights:

Background:

Ph⁺ ALL, the most common genetic subtype of adult ALL, is associated with high relapse risk and poor outcomes. Ph⁺ ALL is increasingly being managed with targeted therapies. Olverembatinib is a third-generation TKI with potent inhibitory activity against wild-type and mutant BCR-ABL1.

Introduction:

POLARIS-1 (NCT06051409) is a global registrational Phase III study designed to evaluate the efficacy and safety of olverembatinib combined with low-intensity chemotherapy in patients with newly diagnosed (ND) Ph⁺ ALL. The primary endpoint of the study was MRD (BCR-ABL/ABL1 \leq 0.01% by qPCR) negativity rate by the end of three induction cycles.

Efficacy Results:

- As of July 18, 2025, among 53 efficacy-evaluable patients, 50 (94.3%) achieved a CR or CR with incomplete hematologic recovery by the end of induction therapy. The best MRD negativity and MRD-negative CR rates were 66.0% and 64.2%, respectively.
- IKZF1^{plus} (particularly with concurrent BTG1 deletion) is a widely recognized high-risk factor associated with poor prognoses in B-cell ALL (B-ALL) because it can often cause resistance to chemotherapies and a high propensity to relapse. Among the 10 patients in this study who had this genotype, the molecular response rate at the end of the induction therapy was 90% (9/10).

Safety Results: Olverembatinib in combination with low-dose chemotherapy was well tolerated. Common (incidence >15%) grade ≥ 3 treatment-emergent adverse events (TEAEs) were neutropenia (63.6%), thrombocytopenia (56.4%), leukopenia (54.5%), anemia (49.1%), pneumonia (30.9%), hypokalemia (20%), and abnormal hepatic function (16.4%).

Conclusion:

In patients with ND Ph⁺ ALL, olverembatinib in combination with chemotherapy demonstrated an MRD-negative CR rate of 64.2% by the end of the induction therapy and a favorable safety profile.

** Olverembatinib, Lisoftoclax, and APG-5918 are currently under investigation and have not yet been approved by the US FDA.*

About Ascentage Pharma

Ascentage Pharma Group International (NASDAQ: AAPG; HKEX: 6855) (“Ascentage Pharma” or the “Company”) is a global, commercial stage, integrated biopharmaceutical company engaged in the discovery, development and commercialization of novel, differentiated therapies to address unmet medical needs in cancer. The Company has built a rich pipeline of innovative drug products and candidates that includes inhibitors targeting key proteins in the apoptotic pathway, such as Bcl-2 and MDM2-p53, as well as next-generation kinase inhibitors.

The lead asset, Olverembatinib, is the first novel third-generation BCR-ABL1 inhibitor approved in China for the treatment of patients with CML in chronic phase (CML-CP) with T315I mutations, CML in accelerated phase (CML-AP) with T315I mutations, and CML-CP that is resistant or intolerant to first and second-generation TKIs. All indications are covered by the China National Reimbursement Drug List (NRDL). The Company is currently conducting an FDA-cleared, global registrational Phase III trial, or POLARIS-2, of Olverembatinib for CML, as well as global registrational Phase III trials for patients with newly diagnosed Ph⁺ ALL and SDH-deficient GIST patients.

The Company’s second approved product, Lisoftoclax, is a novel Bcl-2 inhibitor for the treatment of various hematologic malignancies. Lisoftoclax is being commercialized in China following National Medical Products Administration (NMPA) approval for the treatment of adult patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) who have previously received at least one systemic therapy including Bruton’s tyrosine kinase (BTK) inhibitors. The Company is currently conducting four global registrational Phase III trials: the FDA-cleared GLORA study of Lisoftoclax in combination with BTK inhibitors in patients with CLL/SLL previously treated with BTK inhibitors for more than 12 months with suboptimal response; the GLORA-2 study in patients with newly diagnosed CLL/SLL; the GLORA-3 study in newly diagnosed, elderly and unfit patients with acute myeloid leukemia (AML); and the GLORA-4 study in patients with newly diagnosed higher-risk myelodysplastic syndrome (HR MDS), a study that was simultaneously cleared by the U.S. FDA, the EMA of the EU, and China CDE.

Leveraging its robust R&D capabilities, Ascentage Pharma has built a portfolio of global intellectual property rights and entered into global partnerships and other relationships with numerous leading biotechnology and pharmaceutical companies, such as Takeda, AstraZeneca, Merck, Pfizer, and Innovent, in addition to research and development relationships with leading research institutions, such as Dana-Farber Cancer Institute, Mayo Clinic, National Cancer Institute and the University of Michigan. For more information, visit <https://ascentage.com/>

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical facts, contained in this press release may be forward-looking statements, including statements that express Ascentage Pharma's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results of operations or financial condition.

These forward-looking statements are subject to a number of risks and uncertainties as discussed in Ascentage Pharma's filings with the SEC, including those set forth in the sections titled "Risk factors" and "Special note regarding forward-looking statements and industry data" in its Registration Statement on Form F-1, as amended, filed with the SEC on January 21, 2025, and the Form 20-F filed with the SEC on April 16, 2025, the sections headed "Forward-looking Statements" and "Risk Factors" in the prospectus of the Company for its Hong Kong initial public offering dated October 16, 2019, and other filings with the SEC and/or The Stock Exchange of Hong Kong Limited we made or make from time to time that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements contained in this presentation do not constitute profit forecast by the Company's management.

As a result of these factors, you should not rely on these forward-looking statements as predictions of future events. The forward-looking statements contained in this press release are based on Ascentage Pharma's current expectations and beliefs concerning future developments and their potential effects and speak only as of the date of such statements. Ascentage Pharma does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.