Ascentage Pharma Presents Data on Olverembatinib in CML-LBP and Ph+ BCP-ALL at ASCO 2026

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ROCKVILLE, Md. and SUZHOU, China, May 31, 2026 (GLOBE NEWSWIRE) -- Ascentage Pharma Group International (NASDAQ: AAPG; HKEX: 6855), a global, commercial-stage, integrated biopharmaceutical company engaged in the discovery, development and commercialization of novel therapies to address unmet medical needs in cancer, today announced results from a Phase Ib study evaluating olverembatinib (HQP1351), the company's core product, in combination with bispecific T-cell engager antibody (immunotherapy) blinatumomab in patients with lymphoid blast phase chronic myeloid leukemia (CML-LBP) or Philadelphia chromosome-positive B-cell precursor acute lymphoblastic leukemia (Ph+ BCP-ALL) were presented in a rapid oral presentation at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting.

The ASCO Annual Meeting is the world's most prominent scientific gathering in the clinical oncology community, showcasing cutting-edge research in clinical oncology and advanced cancer therapies. This year marks Ascentage Pharma's ninth consecutive appearance at the ASCO Annual Meeting. A total of six studies involving three of the Company's key assets were selected for presentation, including three rapid oral presentations.

Data from this rapid oral presentation marks the first disclosure of olverembatinib combined with blinatumomab in international patients. The combination regimen demonstrated encouraging clinical activity in patients with relapsed/refractory Ph+ BCP-ALL or CML-LBP, with strong response rates and minimal residual disease (MRD) clearance. In terms of safety, the combination regimen was generally well tolerated, with a safety profile consistent with individual agent toxicities.

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, newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL), and succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumors (GIST), with two of these studies having been cleared by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). 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 Elias Jabbour, MD, the principal investigator of the study from the Department of Leukemia at The University of Texas MD Anderson Cancer Center, stated: "Patients with relapsed or refractory Ph-positive ALL or CML in lymphoid blast phase have a significant unmet medical need. The promising activity and tolerability observed with the combination of olverembatinib and blinatumomab highlight its potential as a novel, chemotherapy-free strategy in this difficult-to-treat setting."

Yifan Zhai, MD, Chief Medical Officer of Ascentage Pharma, said: "This rapid oral presentation marks the first validation in international patients of the therapeutic potential of olverembatinib combined with blinatumomab in CML-LBP and relapsed/refractory Ph+ BCP-ALL. These two diseases have long been considered among the most difficult-to-treat BCR-ABL-driven hematologic malignancies, representing terminal-stage settings with the poorest prognoses and fewest treatment options. The data presented are highly encouraging and may help to address the longstanding unmet need in blast phase disease. We look forward to advancing this program through further clinical studies and translating these findings into sustained patient benefit. Moving forward, we remain committed to our mission of addressing unmet clinical needs for patients worldwide by accelerating clinical development and bringing safe and effective therapies to patients as soon as possible."

Key highlights from the study presented at the 2026 ASCO Annual Meeting are as follows:

Olverembatinib (HQP1351) combined with blinatumomab in patients with lymphoid blast phase chronic myeloid leukemia (CML-LBP) or Philadelphia chromosome-positive B-cell precursor acute lymphoblastic leukemia (Ph+ BCP-ALL)
Abstract #: 6513
Presentation Type: Rapid Oral Presentation
Session Title: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant
First Author: Elias Jabbour, MD, Department of Leukemia, The University of Texas MD Anderson Cancer Center
Key Highlights:

- **Background:** Olverembatinib has previously demonstrated clinical activity in TKI-resistant Ph+ hematologic malignancies. This study evaluated olverembatinib combined with blinatumomab in patients with relapsed/refractory (R/R) Ph+ B-cell precursor acute lymphoblastic leukemia (Ph+ BCP-ALL) or CML-LBP across global sites.
- **Efficacy Data:** A total of 91% (10/11) of patients achieved complete response (CR) or complete response with incomplete hematologic recovery (CRi). In addition, 67% (8/12) of patients achieved BCR::ABL1 negativity by PCR (≤0.01%), and 80% (8/10) achieved minimal residual disease (MRD) negativity by flow cytometry (≤0.01%).
- **Safety Data:** The combination regimen demonstrated a manageable safety profile, with most adverse events (AEs) being grade 1-2, consistent with the known toxicities of each agent.
- **Conclusion:** This study is the first to demonstrate the feasibility of olverembatinib combined with immunotherapy in international patients with CML-LBP and R/R Ph+ BCP-ALL.

** Olverembatinib is currently under investigation and has 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 include inhibitors targeting key proteins in the apoptotic pathway, such as Bcl-2 and MDM2-p53, next-generation kinase inhibitors, and protein degraders.

The Company's first approved product, 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. It is covered by the China National Reimbursement Drug List (NRDL). Ascentage Pharma is currently conducting an FDA- and EMA-cleared registrational Phase III trial, called POLARIS-2, of olverembatinib for CML, as well as an FDA- and EMA-cleared registrational Phase III trials for patients with newly diagnosed Ph+ ALL, called POLARIS-1, and SDH-deficient GIST patients, called POLARIS-3.

The Company's second approved product, lisaftoclax, is a novel Bcl-2 inhibitor for the treatment of various hematologic malignancies. Lisaftoclax has been approved by China's National Medical Products Administration (NMPA) 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- and EMA- cleared GLORA study of lisaftoclax 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 AML; and the FDA- and EMA-cleared GLORA-4 study in patients with newly diagnosed higher risk MDS.

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/

Cautionary Note Regarding 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 "Cautionary note regarding forward-looking statements" in its Annual Report on Form 20-F for the year ended December 31, 2025, filed with the SEC on April 29, 2026, the sections headed "Forward-looking Statements" and "Risks 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 where the Company's ordinary shares are listed it has made or it makes 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.

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