Ascentage Pharma Presents Updated Clinical Data for Olverembatinib as Second-Line Therapy in CML-CP 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, differentiated therapies to address unmet medical needs in cancer, today announced updated efficacy and safety data from a clinical study of its first approved product, olverembatinib (HQP1351), as a second-line therapy in patients with chronic-phase chronic myeloid leukemia (CML-CP) 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 presented in this rapid oral presentation showed that, at cycle 24, patients with CML-CP treated with olverembatinib achieved a complete cytogenetic response (CCyR) rate of 91.3% and a major molecular response (MMR) rate of 60.9%. Responses deepened over time with longer treatment duration. Olverembatinib demonstrated a stable and manageable safety profile during long-term treatment, with no new safety signals identified. This longer follow-up study has generated more mature and encouraging results, further supporting the efficacy and safety of olverembatinib in patients with CML without the T315I mutation and reinforcing its potential role as a second-line treatment option for patients with CML-CP that failed first-line TKI therapy.

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 tyrosine kinase inhibitor (TKI)-resistant 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 Weiming Li, the Principal Investigator of this study from Union Hospital of Tongji Medical College, Huazhong University of Science and Technology, stated: "Overall, with longer treatment duration, olverembatinib not only helped patients achieve deeper responses, but also continued to provide durable clinical benefit while maintaining a favorable safety and tolerability profile, resulting in good patient adherence. These findings further support its role as a potential second-line treatment option for patients with CP-CML without the T315I mutation and provide stronger evidence for clinical practice. We also look forward to additional long-term follow-up data to further validate its efficacy and safety, and to provide stronger evidence-based support for the standardized use and guideline recommendations of olverembatinib in the second-line treatment setting, helping to deliver more optimized treatment options for patients and clinicians."

Yifan Zhai, MD, Chief Medical Officer of Ascentage Pharma, said: "The updated data presented at ASCO once again demonstrated the consistent performance of olverembatinib in the second-line treatment of CML, further strengthening our confidence in advancing this therapy into earlier lines of treatment. We look forward to continuously accumulating evidence from second-line and earlier-line settings to further optimize the treatment pathway for patients with CML and help to deliver greater clinical benefit, longer survival, and improved quality of life. Moving forward, we will continue to uphold our mission of addressing unmet clinical needs for patients around the world by accelerating clinical development and bringing more 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:
Updated efficacy and safety of Olverembatinib (HQP1351) as second-line therapy in patients with chronic-phase chronic myeloid leukemia (CP-CML)
Abstract #: 6510
Format: Rapid oral presentation
Session Title: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allotransplant

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

- **Research Background:** This is a single-arm, multicenter, open-label study conducted in China, evaluating the efficacy and safety of olverembatinib as a second-line treatment.
- **Efficacy Data:** Among 42 evaluable patients, olverembatinib demonstrated significant and progressively deepening anti-tumor activity, with a best CCyR rate of 76.2% and a best MMR rate of 47.6% at study cutoff. Responses continued to improve with longer treatment duration, reaching 91.3% and 60.9%, respectively, at cycle 24. High response rates were also observed in patients previously treated with second-generation TKIs.
- **Safety Data:** In terms of safety, the overall incidence of treatment-related adverse events was 89.4%, most of which were manageable low-grade events, primarily including but not limited to skin hyperpigmentation, hyperuricemia, and increased creatine phosphokinase. Although some grade ≥3 hematologic toxicities were observed, they were all recoverable through supportive treatment.
- **Conclusion:** Overall, olverembatinib demonstrated durable and progressively deepening efficacy while maintaining a manageable safety profile, highlighting its promising clinical potential.

** 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

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