Ascentage Pharma Presents Its First Dataset on MDM2-p53 Inhibitor Alrizomadlin (APG-115) in Pediatric Solid Tumors at ASCO 2026

05-31-26

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 that the Company presented its first dataset of alrizomadlin (APG-115), an MDM2-p53 inhibitor from the Company's apoptosis-targeted pipeline, as monotherapy or in combination with lisaftoclax (APG-2575) in pediatric patients with relapsed/metastatic rhabdomyosarcoma (RMS) or other soft-tissue sarcomas (STSs), in a rapid oral presentation at the 62nd American Society of Clinical Oncology (ASCO) Annual Meeting.

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

The data presented demonstrated preliminary antitumor activity and a manageable tolerability profile of alrizomadlin in pediatric solid tumors. Results showed that alrizomadlin monotherapy demonstrated initial clinical benefit in pediatric rhabdomyosarcoma (RMS), with one pediatric patient achieving a complete response (CR). In combination with investigational selective Bcl-2 inhibitor lisaftoclax, encouraging antitumor activity was observed, with an objective response rate (ORR) of 23.5% among 17 response-evaluable patients, including one complete response in a patient with Ewing sarcoma and three partial responses (PRs). In terms of safety, alrizomadlin, either as monotherapy or in combination with lisaftoclax, demonstrated a manageable safety profile in pediatric patients with solid tumors.

Alrizomadlin is an orally administered, highly selective MDM2-p53 inhibitor independently developed by Ascentage Pharma. It is the first investigational agent of its class to enter clinical development in China and has global first-in-class potential. By blocking the MDM2-p53 protein-protein interaction, alrizomadlin restores the tumor suppressor activity of p53 and induces apoptosis in tumor cells. Recently, alrizomadlin was officially included by the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) in the Pilot Program for the Support of Anti-tumor Drugs R&D for Kids, also known as the "SPARK Plan," for development in pediatric solid tumors including neuroblastoma, rhabdomyosarcoma, and Ewing sarcoma.

Professor Yizhuo Zhang, principal investigator of the study from the Department of Pediatric Oncology at Sun Yat-sen University Cancer Center, said: "Relapsed/refractory pediatric sarcomas are associated with extremely poor prognosis and substantial unmet medical needs. The data presented at the ASCO meeting demonstrated a favorable tolerability profile and promising anti-tumor effect for alrizomadlin both as monotherapy and in combination with lisaftoclax, with the complete response (CR) cases being particularly encouraging. As a key candidate included in the SPARK Plan, alrizomadlin has the potential to become a first-in-class therapy, address unmet medical needs, and bring new hope for long-term survival to pediatric patients."

Professor Yi Zhang, investigator of the study from the Department of Pediatrics at Beijing Tongren Hospital, Capital Medical University, said: "Treatment options for pediatric solid tumors, especially advanced soft-tissue sarcomas, remain very limited. The clinical data generated by the alrizomadlin combination regimen are therefore particularly meaningful. This apoptosis pathway-targeting therapy demonstrated favorable tolerability and encouraging objective response rates, further supporting the therapeutic potential of dual-target combination approaches in refractory pediatric tumors and providing valuable direction for future precision drug development in pediatric oncology."

Yifan Zhai, MD, Chief Medical Officer of Ascentage Pharma, said: "Pediatric solid tumors continue to represent an area of significant unmet medical need. The data presented at ASCO mark our first presentation of alrizomadlin clinical data in pediatric solid tumor patients and demonstrated encouraging preliminary clinical benefit and tolerability. Importantly, alrizomadlin has already been included by the CDE in the SPARK Plan for potential development in multiple pediatric solid tumors. The data presented provide initial clinical evidence supporting this development strategy. We will continue to advance the related clinical studies with the goal of bringing new treatment options to pediatric patients in urgent need."

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

Alrizomadlin (APG-115) alone or in combination with Lisaftoclax (APG-2575) for the treatment of pediatric patients with relapsed/metastatic rhabdomyosarcoma (RMS) or other soft-tissue sarcomas (STSs)
Abstract #: 10012
Presentation Type: Rapid Oral Presentation

Session Title: Pediatric Oncology II
First Author: Yizhuo Zhang, MD, Department of Pediatric Oncology, Sun Yat-sen University Cancer Center, State Key Laboratory of Oncology in South China, Collaborative Innovation Center for Cancer Medicine
Key Highlights:

- **Research Background:** This multicenter clinical trial conducted in China evaluated the safety and preliminary efficacy of alrizomadlin (APG-115) as monotherapy or in combination with lisaftoclax in heavily pretreated pediatric patients with relapsed/metastatic RMS, Ewing sarcoma (EWS), neuroblastoma (NB), and other solid tumors.
- **Efficacy Data:** In the monotherapy arm, 1 patient with refractory RMS achieved CR. In the combination arm, among 17 response-evaluable pediatric patients with relapsed/refractory solid tumors, the ORR was 23.5%, including 1 CR in a patient with EWS, as well as PRs in 2 patients with RMS and 1 patient with NB. The disease control rate (DCR) was 70.6%.
- **Safety Data:** No dose-limiting toxicities (DLTs) were observed in either the monotherapy or combination arm. Adverse events were primarily gastrointestinal and hematologic, with few serious adverse events and no treatment-related deaths or discontinuations.
- **Conclusion:** The regimen demonstrated a manageable safety profile and preliminary antitumor activity in pediatric solid tumors, supporting further investigation.

** Alrizomadlin 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-

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