Aclaris Therapeutics Announces Top Line Phase 2 Results for its Anti-TSLP Monoclonal Antibody Bosakitug (ATI-045) in Atopic Dermatitis (AD)

November 16, 2026

- The ADMIRATION Trial Did Not Achieve its Primary Endpoint of Percent Change in Eczema Area and Severity Index (EASI) Score from Baseline at Week 24 -

- Aclaris Remains Focused on Prioritizing the Development of its Oral Kinase (ITK) Inhibitors and Anti-TSLP/IL-4Rα Bispecific Antibody ATI-052 -

WAYNE, Pa., Nov. 16, 2026 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel product candidates for immuno-inflammatory diseases, today announced top line results from the Phase 2 ADMIRATION trial that evaluated the efficacy and safety of bosakitug (ATI-045), a humanized anti-thymic stromal lymphopoietin (TSLP) monoclonal antibody, in patients with moderate-to-severe atopic dermatitis. The trial did not achieve the primary or secondary endpoints; however, pharmacodynamic (PD) results showed robust target engagement of TSLP and downregulation of biomarkers related to immune activation including Th1, Th2, and Th17. Bosakitug was generally well tolerated in this trial.

“We are disappointed that the ADMIRATION trial did not overcome the historical challenges of addressing atopic dermatitis with an anti-TSLP monoclonal antibody alone,” said Dr. Neal Walker, Chief Executive Officer of Aclaris. “We are grateful to the patients and investigators whose participation and commitment made this study possible.”

Dr. Walker continued, “These results do not change our development priorities, which remain focused on our oral kinase inhibitors and anti-TSLP/IL-4Rα bispecific antibody ATI-052. First and foremost, we have initiated the Phase 2b trial of our oral ITK/JAK3 inhibitor modzatinib in lichen planus. We’ve also completed the IND-enabling studies for our oral ITK inhibitor ATI-9494 and expect to file the IND this quarter. Lastly, we intend to initiate the Phase 2b trial with ATI-052 in eosinophilic esophagitis in the first quarter of 2027. We expect to achieve numerous important regulatory, clinical, and data milestones throughout 2027 with each of these assets.”

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing a pipeline of novel product candidates to address the needs of patients with immuno-inflammatory diseases who lack satisfactory treatment options. The company has a multi-stage portfolio of product candidates powered by a robust R&D engine. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “anticipate,” “believe,” “expect,” “intend,” “may,” “plan,” “potential,” “will,” and similar expressions, and are based on Aclaris’ current beliefs and expectations. These forward-looking statements include expectations regarding its development plans and expected milestones for ATI-052, modzatinib and ATI-9494, including the timing to initiate its Phase 2b trial of ATI-052 in eosinophilic esophagitis, and the timing to submit the IND for ATI-9494. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, risks associated with interim, top line and preliminary data, Aclaris’ reliance on third parties over which it may not always have full control, Aclaris’ ability to enter into strategic partnerships on commercially reasonable terms, the uncertainty regarding the macroeconomic environment and other risks and uncertainties that are described in the Risk Factors section of Aclaris’ Annual Report on Form 10-K for the year ended December 31, 2025, and other filings Aclaris makes with the U.S. Securities and Exchange Commission from time to time. These documents are available under the “SEC Filings” page of the “Investors” section of Aclaris’ website at www.aclaristx.com. Any forward-looking statements speak only as of the date of this press release and are based on information available to Aclaris as of the date of this release, and Aclaris assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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