Aclaris Therapeutics Initiates Phase 1b Proof-of-Concept Trial in Patients with Asthma with its Novel Bispecific Anti-TSLP/IL-4Rα Antibody ATI-052

February 24, 2026

WAYNE, Pa., Feb. 24, 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 that it has initiated a placebo-controlled Phase 1b proof-of-concept (POC) trial of ATI-052, the Company's potential best-in-class investigational bispecific anti-TSLP/IL-4Rα antibody, in asthma. This announcement follows the recent initiation of the Company's Phase 1b POC trial of ATI-052 in atopic dermatitis (AD). Planning is ongoing for a Phase 2b program encompassing asthma and atopic dermatitis as potential first indications. The Company expects to initiate this program in the second half of 2026.

"The start of 2026 has been a period of strong execution and momentum across our clinical programs, broadly, and with ATI-052 specifically," said Dr. Jesse Hall, Chief Medical Officer of Aclaris. "The positive Phase 1a interim results for ATI-052 exceeded our expectations and demonstrated a strong safety and tolerability profile, extended pharmacokinetics, and concentration-dependent pharmacodynamics even at the lowest dose. Following the January announcement that we had initiated our POC trial in atopic dermatitis, we have now initiated our POC trial in asthma. We expect to provide top line results from both trials in the second half of 2026 and start the Phase 2b program shortly thereafter."

The randomized (3:1), double-blind, placebo-controlled Phase 1b POC trial will evaluate the safety, tolerability, and efficacy of ATI-052 compared to placebo in approximately 16 patients with asthma on GINA (Global Initiative for Asthma) steps 2-4 treatment prior to screening. Endpoints that will be assessed include safety and tolerability parameters; pharmacokinetic parameters; respiratory pharmacodynamic (PD) biomarker assessments including FeNO (fractional exhaled nitric oxide); blood PD biomarker assessments including blood eosinophil count and endogenous cytokines/chemokines and inflammation markers in plasma/serum; and efficacy measures including FEV1.

Top line results from this trial and the ongoing Phase 1b POC trial in AD are expected in the second half of 2026.

About ATI-052

ATI-052 is an investigational humanized anti-TSLP and anti-IL-4Rα bispecific antibody that simultaneously inhibits thymic stromal lymphopoietin (TSLP) and interleukin-4 receptor (IL-4Rα) with high affinity and potency. By targeting TSLP, which sits at the top of the inflammatory cascade, it inhibits a broad range of inflammation; by targeting IL-4Rα, it blocks downstream signaling of both IL-4 and IL-13, which are key cytokines involved in Th2-mediated inflammation and allergic diseases. ATI-052 exhibits potential best-in-class potency and utilizes the same TSLP antigen-binding fragment (Fab) region as the Company's monoclonal antibody bosakitug (ATI-045), retaining the dissociation kinetics, long residence time, and high potency advantages over comparator antibodies, but is engineered to bind more tightly to the neonatal Fc receptor (FcRn) to extend its half-life. ATI-052 has the potential to treat a variety of atopic, immunologic and respiratory diseases. Aclaris has the exclusive worldwide rights to ATI-052, excluding Greater China.

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 for ATI-052, including the timing to report results from its Phase 1b trials of ATI-052 in AD and asthma, the timing to initiate a Phase 2b program including asthma and AD, the potential for ATI-052 to be a best-in-class anti-TSLP/IL-4Rα bispecific monoclonal antibody, and the therapeutic potential for ATI-052 including in other atopic, immunologic and respiratory diseases. 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, potential changes to interim, topline and preliminary data as more subject data become available, 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, 2024, 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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