Aclaris Therapeutics Announces Positive Interim Results of Phase 1a Trial of Anti-TSLP/IL-4Rα Bispecific Antibody ATI-052 Supporting Expedited Clinical Development

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- Positive Interim Results of Phase 1a Single (SAD) and Multiple Ascending Dose (MAD) Trial Reinforce Potential Best-in-Class Potency Advantage of ATI-052 -

- Trial Results Support Potential for Extended Dosing of up to Every Three Months -

- Initiation of Phase 1b Proof-of-Concept (POC) Trials in Atopic Dermatitis (AD) and Asthma Now Expected in First Quarter of 2026; Planning Underway for Advancement of ATI-052 into Phase 2b Trial in AD in the Second Half of 2026 -

- Management to Host a Conference Call to Discuss Update Today at 8:00 AM EST -

WAYNE, Pa., Jan. 06, 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 positive interim results from the first-in-human Phase 1a single (SAD) and multiple ascending dose (MAD) trial of its anti-TSLP/IL-4Rα bispecific antibody ATI-052.

“Aclaris has experienced significant momentum across our pipeline over the past few months; consistent with that strong momentum, we are pleased to report positive interim results from our Phase 1a SAD/MAD trial of ATI-052 that exceeded our expectations,” said Dr. Neal Walker, Chief Executive Officer of Aclaris. “ATI-052 demonstrated a strong safety and tolerability profile, dose proportional pharmacokinetic profile, and concentration-dependent pharmacodynamics even at the lowest dose – all of which support its best-in-class potential in a variety of inflammatory and immunological diseases due to its ability to uniquely impact multiple pathways of inflammation.”

Dr. Walker continued, “These impressive results further validate ATI-052 and reinforce its potential best-in-class potency; given these results, we are rapidly advancing the clinical development of the compound. We expect to initiate Phase 1b proof-of-concept trials in AD and asthma shortly, and planning is already underway for initiation of a Phase 2b trial in AD in the second half of 2026.”

Interim Phase 1a SAD/MAD Results

The randomized, blinded, placebo-controlled Phase 1a portion of the first-in-human study was designed to evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of subcutaneously administered ATI-052 in healthy adults receiving single ascending doses (SAD) and multiple ascending doses (MAD). In the SAD portion, four cohorts of 8 healthy volunteers each were randomized 3:1 to receive a single dose of ATI-052 (30, 120, 360, or 720 mg) or placebo. In the MAD portion, two cohorts of 8 healthy volunteers each were randomized 3:1 to receive five doses of two dose levels of ATI-052 (240 or 480 mg) or placebo administered every 7 days.

Interim results of the Phase 1a portion include:

- ATI-052 was well tolerated and demonstrated a favorable safety profile across all SAD and MAD cohorts, with doses of up to 720 mg.
    - Treatment-emergent adverse events (TEAEs) observed in the trial were predominantly Grade 1.
    - There were no Grade 3 TEAEs related to study drug or serious adverse events; no adverse events led to study discontinuation.
    - The most common TEAE was injection site redness which was self-resolving and generally mild (Grade 1).
    - No conjunctivitis was observed in any cohort.
- ATI-052 exhibited a potential best-in-class PK profile, including at least a 26-day effective half-life.
    - Dose proportional PK was observed across the pharmacologic dose range, including approximately dose proportional increases in Cmax (maximum peak concentration) and AUC (area under the curve; a measure representing total systemic exposure).
- PD results from the first three SAD cohorts validate the potency of ATI-052, including robust target engagement and near complete target occupancy at very low doses. Blood samples were collected on days 1, 4, 8, 22, 43, and 113.
    - At the lowest dose tested (30 mg), ATI-052 demonstrated robust concentration-dependent inhibition of IL-4 and TSLP stimulated CCL17/TARC.
    - At 120 mg, ATI-052 demonstrated complete and sustained inhibition of ex vivo IL-4 and TSLP stimulated CCL17/TARC through week one. Near complete inhibition of TSLP stimulated CCL17/TARC was observed at least three weeks after administration.

- At 360 mg, ATI-052 demonstrated complete and sustained inhibition of ex vivo IL-4 and TSLP stimulated CCL17/TARC through week three. Near complete inhibition of TSLP stimulated CCL17/TARC was observed at least six weeks after administration.

- The combination of PK duration and the strong and sustained PD effect support the potential for up to every three-month dosing.

Imminent Initiation of Phase 1b POC Trials; Phase 2b Planning Underway

The positive interim results of the Phase 1a SAD/MAD trial support rapid advancement of clinical development. Aclaris expects to initiate a Phase 1b POC trial in AD imminently and a Phase 1b POC trial in asthma in the first quarter of 2026. The Company expects top line data from both trials in the second half of 2026.

Planning is also underway for a Phase 2b trial of ATI-052 in AD expected to initiate in the second half of 2026.

Webcast and Conference Call

Aclaris will host a webcast and conference call with slides today at 8:00 AM EST to discuss the interim ATI-052 Phase 1a SAD/MAD results. The live and archived webcast will be available on the Events page of the Company's website: https://investor.aclaristx.com/events. The webcast will be archived on the same page for 30 days following the event. If you would rather access the call via telephone: To register and receive a dial in number and unique PIN to access the live conference call, please follow this link to register online. Upon registering you will receive the dial-in info and a unique PIN to join the call as well as an email confirmation with the details.

About ATI-052

ATI-052 is an investigational humanized anti-TSLP and anti-IL-4Rα bispecific antibody that exhibits high binding affinity to and dual blockade of both the upstream thymic stromal lymphopoietin (TSLP) receptor signal transduction and downstream interleukin-4 receptor (IL-4R) activation thereby inhibiting this central proinflammatory pathway. ATI-052 targets TSLP, which sits at the top of the inflammatory cascade; by targeting IL-4Rα, it blocks both downstream 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 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), potentially extending 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 X (formerly Twitter) at @AclarisTx and 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 initiate and report results from its Phase 1b trials of ATI-052 in asthma and atopic dermatitis, the timing to initiate a Phase 2b trial of ATI-052 in AD, and the therapeutic potential for ATI-052, including the potential to be best-in-class, the potential to show superior activity compared to other therapies, and the potential for dosing of up to three months. 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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