Aclaris Therapeutics Announces Positive Phase 1b Proof-of-Concept Primary Analysis Results for its Anti-TSLP/IL-4Rα Bispecific ATI-052 in Atopic Dermatitis (AD) and Asthma

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- Results Demonstrated Breadth and Rapidity of Response to ATI-052 in Heterogeneous Patient Populations; Pharmacodynamic Results Demonstrated Potential for Additivity/Synergy of Targeting TSLP and IL-4Rα -

- Rapid and Durable Improvement in Skin and Itch Observed in Severe AD Population with ATI-052; Single Dose Rapidly Improved Airway Inflammation and Lung Function in Diverse Asthma Population -

- ATI-052 Demonstrated Favorable Safety and Tolerability Profile Including No Observations of Conjunctivitis -

- Aclaris to Prioritize Development in Eosinophilic Esophagitis (EoE), Consistent with Development Strategy -

- Aclaris to Host Conference Call this Morning at 8:00 AM ET-

WAYNE, Pa., Oct. 27, 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 primary analysis results from the Phase 1b proof-of-concept (POC) trials of its anti-TSLP/IL-4Rα bispecific antibody ATI-052 in atopic dermatitis and asthma. Both trials demonstrated strong proof-of-concept with rapid and broad responses to ATI-052, further validating the additive/synergistic potential of simultaneously targeting TSLP, IL-4, and IL-13 with a bispecific anti-TSLP/IL-4Rα antibody, and achieved the primary objective, showing a favorable safety profile including no observations of conjunctivitis. Slides accompanying this announcement will be available for download at the time of the conference call here.

Aclaris intends to prioritize Phase 2b development of ATI-052 initially in EoE, where the Company believes a focused development program is well aligned with its development strategy and disciplined capital management.

“These strong results convey ‘the art of the possible’ with this bispecific mechanism in heterogeneous diseases across diverse patient populations and support that this is a potent, broadly acting compound with potential best-in-class activity,” said Dr. Neal Walker, Chief Executive Officer of Aclaris. “Across heterogeneous patient populations, we observed breadth and depth of response, normalization of the immune proteome, encouraging early durability, evidence of potential synergy of targets, and a favorable safety profile associated with ATI-052 – all of which clarify its potential across indications. Consistent with our development strategy, we intend to prioritize initiating a Phase 2b trial in EoE early next year and provide an update on plans for a potential additional indication in the near term.”

Primary Analysis Results: Safety

ATI-052 was well tolerated across both trials and demonstrated a favorable safety profile. Treatment-emergent adverse events (TEAEs) observed in these POC trials were predominantly Grade 1. There were no Grade 3 or 4 TEAEs, and no adverse events led to study discontinuation. Injection site reactions (ISR) were transient, almost exclusively Grade 1, and observed at a low frequency. No conjunctivitis was observed.

Phase 1b POC Trial in Atopic Dermatitis (AD)

The randomized (3:1), double-blind, placebo-controlled Phase 1b trial evaluated the safety and tolerability of ATI-052 compared with placebo in 14 patients with severe AD. Enrolled patients received five weekly doses of 480 mg of ATI-052 or placebo from weeks 0 through 4, and endpoints for the primary analysis were assessed at day 57. Four patients were excluded from the prespecified per-protocol analysis for reasons defined before unblinding: Two in the ATI-052 arm (only two doses taken; eligibility criteria not met) and two in the placebo arm (both began rescue medication early on). Among per-protocol patients in the active arm, 78% had severe disease at baseline, as defined by a score of 4 on the Validated Investigator’s Global Assessment (vIGA), setting a high bar for success.

Primary Analysis Results: AD

Eczema Area and Severity Index (EASI) Score

- Patients treated with ATI-052 experienced a 45% placebo-adjusted mean change in EASI score from baseline at day 57 (absolute change of 58% in the active arm vs 13% in the placebo arm). Responses were durable for the subset of patients with available data at week 16 (follow up ongoing).
- Patients treated with ATI-052 experienced a 78% placebo-adjusted EASI-50 at day 57. Of those, 100% of patients with a baseline severity of vIGA 3 achieved placebo-adjusted EASI-50 at day 57 compared to 71% of patients with a baseline severity of vIGA 4.

Peak Pruritus Numerical Rating Scale (PP-NRS)

- Itch relief emerged in the first week and continued to deepen through week 10 in patients with available data despite high

baseline disease severity. At week 4, patients that received ATI-052 experienced a 40% placebo-adjusted and absolute mean improvement from baseline in itch (PP-NRS).

- Patients that received ATI-052 experienced a 43% placebo-adjusted mean improvement in itch (PP-NRS) at day 57 (38% absolute improvement in the active arm vs a 5% worsening in the placebo arm).
- At day 57, 33% of patients experienced a placebo-adjusted mean improvement of ≥4-points in itch (PP-NRS4).

“These ATI-052 data in AD are very noteworthy, not only in strength of response at day 57 but also in rapidity and durability of response,” said Dr. Michael Cameron, M.D., FAAD, CEO of Equity Medical and Assistant Clinical Professor, Department of Dermatology at Mount Sinai in New York, and an investigator in the trial. “Given the mechanism of ATI-052, one would expect reductions in EASI and itch from baseline to be rapid and sustained due to blockade of IL-4 and IL-13 via their shared receptor IL-4Rα, and durable through blockade of the TSLP alarmin. This is consistent with my experience during the trial. For example, one of my longstanding refractory patients responded quickly to ATI-052 and had a durable response that lasted months beyond their last dose. This bodes well for the mechanism in future clinical trials.”

Pharmacodynamic (PD) Results

- 95% normalization in the lesional skin proteome was observed at week 8 in patients that received ATI-052, with immune protein expression resembling that of non-lesional skin.
- ATI-052 broadly downregulated pathways, with modulation across multiple inflammatory mediators in AD, including Th1, Th2 and Th17/Th22, fibrosis/ECM remodeling, and itch-associated molecular pathways.
- ATI-052 produced a pronounced reduction of the established dupilumab biomarkers, additionally suppressing Th1, Th17 innate, and myeloid pathways, suggesting a potential best-in-class footprint.

“These ATI-052 pharmacodynamic biomarker results in patients with AD are clear, and significantly correlated to the efficacy results,” said Emma Guttman, M.D., Ph.D., Waldman Professor of Dermatology and Immunology and Health System Chair of the Kimberly and Eric J. Waldman Department of Dermatology at the Icahn School of Medicine at Mount Sinai in New York City. “Among the most important findings were the overall improvements to the immune proteome in patients receiving ATI-052; key immune proteins were significantly downregulated by ATI-052 compared to placebo, potentially highlighting the contribution of added benefit of blocking TSLP in this indication, with the proteomic phenotype of lesional skin closely resembling that of non-lesional skin already at week 8. These results, including ATI-052’s ability to modulate all three T helper cell related markers, are suggestive of early potent anti-inflammatory clinical activity.”

Phase 1b POC Trial in Asthma

The randomized (3:1), double-blind, placebo-controlled Phase 1b trial evaluated the safety and tolerability of a single 480 mg dose of ATI-052 compared with placebo in 16 patients with mild-to-moderate asthma and baseline fractional exhaled nitric oxide (FeNO) of at least 35 parts per billion (ppb). Endpoints were assessed through day 29.

Primary Analysis Results: Asthma

Fractional Exhaled Nitric Oxide (FeNO)

- Following a single dose of ATI-052, patients experienced a rapid 59% mean absolute reduction in FeNO (45 ppb) only 15 days after administration compared to 15% in the placebo arm, and a 40% reduction at day 29.
- 58% of patients on ATI-052 achieved FeNO normalization (≤25 ppb) at day 15 after a single dose, highlighting the rapid onset of response.

Forced Expiratory Volume in One Second (FEV1)

- Following a single ATI-052 dose, patients responded rapidly, experiencing a placebo adjusted and absolute mean improvement of 200 ml in FEV1 only 15 days after administration.
- In a post hoc subgroup analysis of the enrolled patients with FEV1 of <80% at baseline with reversibility, which models the typical Phase 2b/3 eligible population of patients, an absolute mean improvement in FEV1 of 350 ml from baseline was observed at day 15 compared to a worsening of FEV1 of -140 ml in the placebo arm.

“In such a Phase 1b trial, the goals are to ensure safety and to develop some encouraging signals; in this case, the results are significantly better than encouraging,” said Dr. Chris Brightling, Clinical Professor in Respiratory Medicine at the University of Leicester and Deputy Director and Respiratory and Infection Theme Lead, NIHR Biomedical Research Centre: Leicester. “Of particular interest are the rapid improvements in the breath biomarker FeNO, both in the overall population and when stratified by baseline eosinophils, and the lung function test FEV1, with maximum effects that are at least as good if not improving on those seen by comparator compounds.”

Webcast and Conference Call

Aclaris will host a webcast and conference call with slides today at 8:00 AM ET to discuss the Phase 1b POC primary analysis results in asthma and

AD. 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 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. The TSLP binding interface of ATI-052 allows it to extensively bind TSLP, uniquely binding all six light chain and heavy chain CDRs. ATI-052 demonstrates very slow dissociation kinetics from TSLP with a residence time up to 116x longer than comparator antibodies. It 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 its intention to prioritize development of ATI-052 initially in EoE, the timing to initiate a Phase 2b trial of ATI-052 in EoE and the timing and plans to pursue development of ATI-052 in additional indications, the therapeutic potential for ATI-052, including the potential for ATI-052 to be best-in-class, the potential for ATI-052 to provide additive or synergistic activity through the simultaneous inhibition of TSLP and IL-4Rα, and the potential for ATI-052 to treat 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, risks associated with interim, topline 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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