Aclaris Therapeutics Initiates Phase 1a/1b Program for its Novel Bispecific Antibody ATI-052

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- Potential Best-In-Class Bispecific Antibody ATI-052 Targets Both Thymic Stromal Lymphopoietin (TSLP) and Interleukin-4 Receptor (IL-4R) -

WAYNE, Pa., June 23, 2025 (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 1a/1b program for ATI-052, the Company's potential best-in-class investigational bispecific anti-TSLP/IL-4R antibody. The program will consist of a Phase 1a single and multiple ascending dose (SAD/MAD) portion in healthy volunteers, followed by an expected Phase 1b proof of concept portion.

"This is an important milestone in the development of ATI-052, our uniquely potent bispecific anti-TSLP/IL-4R antibody, for which we recently received IND clearance from the U.S. Food and Drug Administration," said Dr. Jesse Hall, Chief Medical Officer of Aclaris. "This novel bispecific antibody was designed to exhibit high binding affinity to, and dual blockade of, both upstream and downstream targets to selectively inhibit central proinflammatory pathways involved in Th2-mediated inflammation and allergic diseases. We expect to complete the Phase 1a SAD/MAD portion by year-end 2025 and provide top line results in early 2026, followed by the top line results from the Phase 1b portion in the second half of 2026."

The randomized, blinded, placebo-controlled Phase 1a portion is designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of subcutaneously administered ATI-052 initially in healthy adults receiving single ascending doses (SAD) and multiple ascending doses (MAD). The Phase 1b proof-of-concept assessment in up to two undisclosed indications is expected to follow the Phase 1a SAD/MAD portion of the program.

Bispecific antibodies are engineered to have two distinct binding domains that can bind to two targets simultaneously. This dual binding and pathway inhibition potentially enhances efficacy over traditional monoclonal antibodies, with broad applications for the potential treatment of many immune-modulated diseases.

About ATI-052

ATI-052 is an investigational humanized anti-TSLP and anti-IL-4R 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-4R, 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) 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 of reporting results from the Phase 1a portion and the Phase 1b portion, the potential for the Phase 1b portion to evaluate ATI-052 in up to two undisclosed indications, the potential for ATI-052 to be a best-in-class anti-TSLP/IL-4R bispecific monoclonal antibody, and the therapeutic potential for ATI-052. 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, 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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