Aclaris Therapeutics Secures U.S. Food and Drug Administration IND Clearance for ATI-052, Enabling Advancement of its Novel Bispecific Anti-TSLP/IL-4R Investigational Antibody

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- Initiation of Upcoming Phase 1a/1b Clinical Trial Expected in the Second Quarter of 2025 -

WAYNE, Pa, April 22, 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 the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for a Phase 1a/1b clinical trial of ATI-052, a potential best-in-class bispecific anti-TSLP/IL-4R monoclonal antibody.

“Therapeutic innovation is at the core of the important work we do at Aclaris, and bispecific antibodies represent a groundbreaking innovation in immunotherapy that we believe will evolve the therapeutic armamentarium in a variety of settings,” said Dr. Hugh Davis, Aclaris’ President and Chief Operating Officer. “Key to our license agreement with Biosion, Inc. were the rights to ATI-052, a potential best-in-class investigational bispecific antibody that exhibits a high binding affinity to, and dual blockade of, both the TSLP ligand and the IL-4 receptor, and as such inhibits a key central proinflammatory pathway. Developing bispecific antibodies for immuno-inflammatory disorders is of significant interest to Aclaris, and the clearance of the ATI-052 IND by the FDA is an important milestone in that regard.”

The randomized, blinded, placebo-controlled, Phase 1a/1b clinical trial will evaluate single and multiple ascending doses of ATI-052 followed by a proof-of-concept portion in an undisclosed indication. The Company expects to initiate the trial in the second quarter of 2025.

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 Investigational New Drug Applications (INDs)

An IND application is a request submitted to the FDA seeking permission to test a new drug in humans. The application includes detailed information about the investigational drug, its composition, pharmacology and toxicology data from preclinical studies, proposed clinical trial protocols, and information on manufacturing and quality control. Organizations can initiate a clinical trial in the U.S. only with IND clearance from the FDA.

About ATI-052

ATI-052 is an investigational, potential best-in-class anti-TSLP/IL-4R bispecific monoclonal antibody being developed to treat certain immuno-inflammatory diseases. ATI-052 targets thymic stromal lymphopoietin (TSLP) and interleukin-4 receptor (IL-4R) that blocks both the upstream TSLP receptor signal transduction and downstream IL-4R activation which inhibits both IL-4 and IL-13 signaling, thereby inhibiting this central proinflammatory pathway and potentially offering enhanced efficacy through dual pathway inhibition. ATI-052 utilizes the same TSLP antigen-binding fragment (Fab) region as bosakitug (ATI-045), Aclaris’ investigational anti-TSLP monoclonal antibody, 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 anticipated design and timing for its Phase 1a/1b trial of ATI-052, the potential for ATI-052 to be a best-in-class anti-TSLP/IL-4R bispecific monoclonal antibody and the therapeutic potential of 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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