Aclaris Therapeutics Announces First Patient Dosed in Phase 2a Clinical Trial of ATI-2138, an Investigational Oral Covalent ITK/JAK3 Inhibitor for the Treatment of Moderate to Severe Atopic Dermatitis

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WAYNE, Pa., Sept. 17, 2024 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases, today announced that the first patient has been dosed in Aclaris' Phase 2a clinical trial of ATI-2138, an investigational oral covalent inhibitor of interleukin-2-inducible T cell kinase (ITK) and Janus kinase (JAK) 3, for the treatment of moderate to severe atopic dermatitis (AD).

"We are thrilled to have dosed the first patient in this clinical trial, marking an important milestone for our ITK inhibitor programs," said Dr. Neal Walker, Interim President & CEO and Chair of the Board of Directors of Aclaris. "ATI-2138 has a unique mechanism of action as a dual inhibitor of both ITK and JAK3. We look forward to evaluating the potential of ATI-2138 as a treatment option for patients with atopic dermatitis."

The Phase 2a trial is an open-label study to investigate the safety, tolerability, pharmacokinetics, efficacy, and pharmacodynamics of ATI-2138 administered over 12 weeks in patients with moderate to severe atopic dermatitis. Aclaris' planned enrollment for this trial is approximately 15 subjects, and the trial will be conducted in the United States. The primary endpoints are safety-related parameters. Secondary endpoints include Eczema Area and Severity Index (EASI) response measures, including EASI-50, EASI-75, and EASI-90, Validated Investigator Global Assessment (vIGA) response, body surface area (BSA) response and other pertinent efficacy related measures. Aclaris expects topline data from this trial in the first half of 2025.

About ATI-2138

ATI-2138 is an investigational oral covalent inhibitor of ITK, and JAK3 for the potential treatment of T cell-mediated autoimmune diseases. The ITK/JAK3 compound interrupts T cell signaling through the combined inhibition of ITK/JAK3 pathways in lymphocytes. Aclaris is developing ATI-2138 as a potential treatment for T cell-mediated autoimmune diseases.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates to address the needs of patients with immuno-inflammatory diseases who lack satisfactory treatment options. The company has a multi-stage portfolio of drug candidates powered by a robust R&D engine exploring protein kinase regulation. For additional information, please visit www.aclaristx.com.

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 ATI-2138 as a potential treatment for moderate to severe atopic dermatitis and other T cell-mediated diseases, and the clinical development of ATI-2138, including the timing for topline data. 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, 2023, 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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