



Aclaris Therapeutics Completes Enrollment in its Phase 2a Clinical Trial of ATI-1777 for Moderate to Severe Atopic Dermatitis

March 15, 2021

- **Enrollment Completed**
- **Data Expected Mid-Year 2021**

WAYNE, Pa., March 15, 2021 (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 it has completed enrollment in its Phase 2a clinical trial of ATI-1777, an investigational topical "soft" Janus kinase (JAK) 1/3 inhibitor, for the potential treatment of moderate to severe atopic dermatitis (AD) (ATI-1777-AD-201).

ATI-1777-AD-201 is a Phase 2a, multicenter, randomized, double-blind, vehicle-controlled, parallel-group clinical trial to determine the efficacy, safety, tolerability and pharmacokinetics of ATI-1777 in subjects with moderate to severe AD. Subjects will apply ATI-1777 or vehicle twice daily for 4 weeks. The primary endpoint is the percentage change from baseline in the Eczema Area and Severity Index (EASI) score at week 4.

"This is an important trial because it explores whether a topical JAK inhibitor can successfully treat moderate to severe AD rather than mild disease," said Dr. David Gordon, Chief Medical Officer of Aclaris. "We hope to establish that a topical JAK inhibitor can safely and effectively treat moderate to severe AD while limiting systemic exposure."

Dr. Neal Walker, President and CEO of Aclaris, said, "This is another important milestone for the Company for its second development program generated by KINect[®], our proprietary drug discovery platform. Earlier this year, we announced our positive preliminary topline results for our Phase 2a clinical trial of ATI-450, our investigational oral MK2 inhibitor, for moderate to severe rheumatoid arthritis. We are very pleased with the progress of our development programs."

Aclaris expects data from this trial by mid-year 2021.

About ATI-1777

ATI-1777 is an investigational topical "soft" Janus kinase (JAK) 1/3 inhibitor. "Soft" JAK inhibitors are designed to provide JAK inhibition at the site of application and be rapidly metabolized in systemic circulation. Aclaris plans to develop ATI-1777 as an emollient-containing spray formulation. Aclaris is developing ATI-1777 as a potential treatment for moderate to severe atopic dermatitis.

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 "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-1777 as a potential treatment for moderate to severe atopic dermatitis and the clinical development of ATI-1777, including the timing of data for ATI-1777-AD-201. 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 COVID-19 pandemic 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, 2020 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 <http://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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Source: Aclaris Therapeutics, Inc.