Aclaris Therapeutics Completes Enrollment in Phase 2b Study of ATI-1777 for Mild to Severe Atopic Dermatitis (ATI-1777-AD-202)

October 3, 2023

- Top-line Data Anticipated Around Year End

WAYNE, Pa., Oct. 03, 2023 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases, today announced the completion of enrollment into ATI-1777-AD-202, its Phase 2b trial of its investigational topical "soft" Janus kinase (JAK) 1/3 inhibitor, ATI-1777, in patients with mild to severe atopic dermatitis. Aclaris anticipates releasing top-line efficacy, safety and other preliminary data from this trial around the end of this year.

"We are very pleased to have completed the enrollment stage of our Phase 2b trial of ATI-1777 in atopic dermatitis, one of our two lead clinical development assets," stated Gail Cawkwell, M.D., Ph.D., Aclaris' Chief Medical Officer. "With this achievement, we are positioned for a very exciting year end for our two lead assets, first with the data read-out of our Phase 2b trial of zunsemetinib (ATI-450) in rheumatoid arthritis expected in November, followed by the top-line results of the ATI-1777 trial expected around year end."

ATI-1777 is a topical JAK inhibitor designed to minimize systemic exposure and delivered in a spray-on solution. The Phase 2b trial follows the successful four-week Phase 2a trial in moderate to severe atopic dermatitis which demonstrated meaningful improvement in the modified Eczema Area and Severity Index (EASI) and minimal measurable systemic exposure with a 2% formulation applied twice daily. The Phase 2b vehicle-controlled trial in atopic dermatitis further explores the concentration range (0.5%, 1% and 2%), as well as a once-daily regimen using the 2% formulation. The trial enrolled 250 patients with mild, moderate or severe AD, including adults and children as young as 12-years-old, across 34 clinical trial sites in the U.S. The primary efficacy endpoint is the percent change in EASI over a period of 4 weeks. Secondary measures of efficacy, as well as safety and pharmacokinetics, will also be assessed.

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 mild to severe atopic dermatitis. ATI-1777 is currently in clinical development, and its safety and efficacy have not been evaluated by regulatory authorities.

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 Aclaris' expectations regarding the timing of reporting results from ATI-1777-AD-202 and its Phase 2b trial of zunsemetinib (ATI-450) in rheumatoid arthritis, and Aclaris' plans to develop ATI-1777 as an emollient-containing spray formulation for the potential treatment of atopic dermatitis, and other statements that are not historical fact. 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, 2022 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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Source: Aclaris Therapeutics, Inc.