



Aclaris Therapeutics Submits Investigational New Drug Application for ATI-1777, a Topical “Soft” JAK1/3 Inhibitor, for the Treatment of Moderate to Severe Atopic Dermatitis

July 7, 2020

WAYNE, Pa., July 07, 2020 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates for immuno-inflammatory diseases, today announced that it has submitted an Investigational New Drug (IND) Application to the U.S. Food and Drug Administration (FDA) for ATI-1777, an investigational topical “soft” Janus kinase (JAK) 1/3 inhibitor, for the treatment of moderate to severe atopic dermatitis (AD). ATI-1777 is another compound generated from the Aclaris KINect™ drug discovery platform, and was specifically developed as a topical “soft” drug.

“We are very pleased to have achieved another development milestone with the submission of this IND and look forward to exploring the therapeutic potential of ATI-1777 in patients with moderate to severe AD,” said Dr. David Gordon, Chief Medical Officer of Aclaris. “ATI-1777 is designed to be active in the skin but rapidly metabolized in the systemic circulation, with the goal of developing a medicine that is efficacious in the treatment of AD while limiting systemic exposure.”

If the IND is allowed, Aclaris plans to initiate a Phase 1/2a multicenter, randomized, double-blind, vehicle-controlled trial to investigate the safety, tolerability, pharmacokinetics, and efficacy of topically applied ATI-1777 in subjects with moderate to severe AD in the second half of 2020. The primary endpoint will assess efficacy at 4 weeks.

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 the systemic circulation. Aclaris plans to develop ATI-1777 as an emollient-containing spray formulation. If the IND is allowed, Aclaris plans to develop 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 and follow Aclaris on LinkedIn or Twitter @aclaristx.

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 patients with moderate to severe atopic dermatitis and the clinical development of ATI-1777. 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, 2019, Aclaris’ Quarterly Report on Form 10-Q for the quarter ended March 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.