Aclaris Therapeutics Initiates Phase 1 Clinical Trial for ATI-50001, an Investigational JAK Inhibitor, for the Treatment of Alopecia Totalis and Alopecia Universalis

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MALVERN, Pa., Dec. 07, 2016 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (Nasdaq:ACRS), today announced that its Investigational New Drug (IND) Application for ATI-50001, an orally administered investigational Janus Kinase (JAK) inhibitor, for the potential treatment of alopecia totalis and alopecia universalis has cleared the 30-day review period by the U.S. Food and Drug Administration, allowing Aclaris to proceed with its planned Phase 1 clinical trial Aclaris has initiated dosing of patients in this pharmacokinetic/pharmacodynamic (PK/PD) trial. The trial is being conducted in 12 healthy volunteers to evaluate the safety, bioavailability, and pharmacodynamics of ATI-50001.

“We are excited to have achieved this important milestone,” said Christopher Powala, Chief Operating Officer. “We look forward to developing ATI-50001 as a potential oral treatment for these severe phenotypes of alopecia areata.”

Alopecia areata is an autoimmune disease characterized by patchy, non-scarring hair loss on the scalp and body. The scalp is the most commonly affected area, and the National Alopecia Areata Foundation estimates that 6.8 million patients in the United States have had or will develop alopecia areata during their lives.[1] The disease affects both women and men; two-thirds of affected individuals are younger than 30 years old at the time of onset of disease. Alopecia areata can be associated with serious psychological consequences, including anxiety and depression.[2] A significant unmet need exists for a safe and efficacious treatment.

Aclaris has exclusively licensed several patents and patent applications involving novel selective JAK 1/3 inhibitors, including a patent portfolio from Rigel Pharmaceuticals, Inc. that covers ATI-50001 as well as ATI-50002, a topical formulation also being developed as a potential treatment for alopecia areata. In addition, Aclaris has exclusively licensed a patent portfolio from JAKPharm and Key Organics directed to novel covalently binding, highly selective JAK 3 inhibitors. Finally, Aclaris has exclusively licensed a patent portfolio from Columbia University directed to methods of using JAK inhibitors for the treatment of alopecia areata, androgenetic alopecia, and other dermatological conditions. This portfolio includes a recently issued U.S. patent directed to methods of treating alopecia areata, androgenetic alopecia and other hair loss disorders by administering ruxolitinib, and a recently issued patent in Japan directed to pharmaceutical compositions comprising ruxolitinib, baricitinib or other JAK inhibitors for use in treating alopecia areata, androgenetic alopecia and other hair loss disorders.

[1] National Alopecia Areata Foundation, https://www.naaf.org/alopecia-areata. Last accessed October 24, 2016.

[2] Hunt, Nigel and McHale, Sue. The psychological impact of alopecia. British Medical Journal. 2005 Oct 22;331: 951-3

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage dermatologist-led pharmaceutical company focused on identifying, developing, and commercializing innovative and differentiated drugs to address significant unmet needs in dermatology. Aclaris is based in Malvern, Pennsylvania and more information can be found by visiting Aclaris’ website at 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", "may", "plan," "potential," "will," and similar expressions, and are based on Aclaris' current beliefs and expectations. These forward-looking statements include expectations regarding Aclaris’ development programs in skin and hair conditions, and the clinical development of JAK inhibitors. 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, 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, 2015, Aclaris' Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, and other filings Aclaris makes with the U.S. Securities and Exchange Commission from time to time. These documents are available under the "Financial Information" section of the Investors page 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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