Aclaris Therapeutics Announces First Patient Dosed in a Pilot Study with ATI-502 Topical in Patients with Androgenetic Alopecia

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WAYNE, Pa., April 23, 2018 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led biopharmaceutical company committed to identifying, developing, and commercializing innovative therapies to address significant unmet needs in aesthetic and medical dermatology and immunology, today announced the initiation of a Phase 2 open-label study of ATI-502, a topical Janus Kinase (JAK) 1/3 inhibitor (ATI-502 Topical), in patients with androgenetic alopecia (AGA), a condition characterized by a genetically determined male/female-pattern baldness.

This trial will evaluate the safety, tolerability and effect of ATI-502 Topical applied twice daily in 24 adult subjects (12 male, and 12 female) with androgenetic alopecia. This 30-week trial will be conducted at 3 investigational centers within the United States.

JAK signaling has been implicated in maintaining the hair cycle in its resting phase (telogen) in mice. Treatment of mouse telogen skin with topical JAK inhibitors prompts telogen follicles to enter the active growth phase (anagen). Hair loss disorders, such as AGA, in which the hair follicles are arrested in telogen phase, may be responsive to treatment with topical JAK inhibitors to promote their entry into anagen, and thus result in the initiation of hair growth.[1]

"This trial is the first step in evaluating the potential clinical benefit of ATI-502 topical solution in treating patients with AGA, or male/female pattern baldness," said Dr. Stuart Shanler, Chief Scientific Officer of Aclaris. "This is an important step forward in understanding the clinical utility of our JAK inhibitors in patients with AGA."

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a dermatologist-led biopharmaceutical company committed to identifying, developing, and commercializing innovative therapies to address significant unmet needs in dermatology, both aesthetic and medical, and immunology. Aclaris' focus on market segments with no FDA-approved medications or where treatment gaps exist has resulted in the first FDA-approved treatment for raised seborrheic keratoses and several clinical programs to develop medications for the potential treatment of common warts, alopecia areata, and vitiligo. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn.

About Androgenetic Alopecia

Androgenetic alopecia (AGA), also known as male pattern baldness or female pattern hair loss, is the most common form of hair loss.[2] The condition may affect up to 70% of men and 40% of women, beginning at some point in their adult lives.[3] Male pattern baldness usually involves hairline recession and balding of the highest point of the head, while female pattern hair loss tends to manifest as thinning hair over the top of the scalp. Susceptibility to AGA is largely determined by genetics, though environmental factors may play a minor role. Affected individuals can be highly motivated to seek treatment, due to negative image perceptions.[3] Currently available treatment procedures and medications are not optimal for some patients for various reasons, such as adverse reactions and contraindications. There is an unmet need for an additional safe and effective treatment option for AGA.

1 S. Harel, C. A. Higgins, J. E. Cerise, Z. Dai, J. C. Chen, R. Clynes, A. M. Christiano, Pharmacologic inhibition of JAK-STAT signaling promotes hair growth. *Sci. Adv*. 1, e1500973 (2015).

2 Ghanaat M, Types of Hair Loss and Treatment Options. *South Med J*. 2010;103(9):917-921.

3 http://www.skintherapyletter.com/alopecia/promising-therapies/. Last accessed April 9, 2018.

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' clinical development of its JAK inhibitor drug candidates. 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, 2017 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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