Aclaris Therapeutics Announces Positive 6-Month Results from a Phase 2 Open-Label Clinical Trial of ATI-502 Topical in Patients with Androgenetic Alopecia (Male/Female Pattern-Baldness)

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WAYNE, Pa., June 17, 2019 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a physician-led biopharmaceutical company focused on immuno-inflammatory and dermatological diseases, today announced positive results from a Phase 2 open-label clinical trial of ATI-502 (AGA-201), an investigational topical Janus Kinase (JAK) 1/3 inhibitor, in patients with androgenetic alopecia (AGA), a condition commonly known as male/female-pattern baldness.

The trial evaluated ATI-502 in women and men with AGA. Subjects aged 18-50 years (n=31) applied ATI-502 to their scalp twice daily for 26 weeks. Twenty-three subjects completed 6 months of treatment. Twenty subjects (14 male, 6 female) had evaluable hair counts, and twenty-two (15 male and 7 female) recorded investigator global assessment (IGA) and subject self-assessment (SSA) scores.

The primary endpoint was the mean change from baseline in non-vellus target area hair count (TAHC) at week 26. The overall change was an increase of 8.6 hairs/cm^2. TAHC increase was 15.3 hairs/cm^2 in female subjects and 5.6 hairs/cm^2 in male subjects.

The secondary endpoints included an IGA and SSA. Subjects who experienced increased hair growth were given a score of +1 or better on the IGA and SSA (+1 = slightly increased hair growth, +2 = moderately increased hair growth, and +3 = greatly increased hair growth). Based on these endpoints, investigators rated 73% of subjects (16/22) as experiencing increased hair growth, and 82% of subjects (18/22) rated themselves as experiencing increased hair growth. ATI-502 was well-tolerated. There were no treatment-related serious adverse events. There was one unrelated serious adverse event of breast cancer reported, and one patient withdrew for treatment-related alopecia in week one.

“The combination of the TAHC data, the investigator and subject assessments, and our own internal review of the formal photography, suggest topical JAK inhibition is a viable approach to treating AGA,” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris. “This finding demonstrates that inhibiting a non-hormonal and inflammatory-mediated pathway may be an option for the treatment of AGA.”

“There has been no novel drug approved for the treatment of AGA for decades. These data are encouraging and suggest ATI-502 may be a potential treatment for patients with AGA – especially women,” said Dr. Janet Roberts of Northwest Dermatology Institute, Portland, Oregon, a Principal Investigator in the clinical trial.

Next Steps:

- The 12-month results from this trial are expected by year end 2019.
- Through recent formulation work, Aclaris can achieve significantly higher topical concentrations of ATI-502.
- As such, Aclaris believes the next step is initiating a double-blind, randomized, controlled Phase 2 dose-ranging clinical trial with higher concentrations of ATI-502, with potentially a female focus, in the first half of 2020.

Company to Host Conference Call

Management will conduct a conference call at 8:00 AM ET today to review these Phase 2 results and related matters. The conference call will be webcast live over the Internet and can be accessed by logging on to the “Investors” page of the Aclaris Therapeutics website, www.aclaristx.com, prior to the event. A replay of the webcast will be archived on the Aclaris Therapeutics website for 30 days following the call.

To participate on the live call, please dial (844) 776-7782 (domestic) or (661) 378-9535 (international), and reference conference ID 8887134 prior to the start of the call.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a physician-led biopharmaceutical company committed to addressing the needs of people with immuno-inflammatory and dermatological diseases who lack satisfactory treatment options. The company’s diverse and multi-stage portfolio includes two FDA-approved medicines, one late-stage investigational medicine, and a pipeline powered by a robust R&D engine exploring protein kinase regulation. Aclaris Therapeutics’ active development programs focus on areas where significant treatment gaps exist, such as common warts, alopecia areata, and vitiligo. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn or Twitter @aclaristx.

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, affecting approximately 50 million men and 30 million women in the U.S.[1,3] The condition may affect up to 70% of men and 40% of women, beginning at some point in their adult lives.[2] 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.[1,2] Susceptibility to AGA is largely determined by genetics, though environmental factors may play a minor role.[2] While AGA is widespread, negative image perceptions make individuals with AGA highly motivated to seek diagnosis and treatment.[2] Currently available treatment procedures can be invasive and costly and are not optimal for some patients for various reasons, such as adverse reactions and contraindications.

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

2 McElwee, K. J., & Shapiro, J. Promising Therapies for Treating and/or Preventing Androgenic Alopecia. https://www.skintherapyletter.com/alopecia/promising-therapies/. Published June 1, 2012. Accessed May 13, 2019.

3 National Institutes of Health. Androgenetic alopecia. https://ghr.nlm.nih.gov/condition/androgenetic-alopecia. Accessed May 13, 2019.

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 the clinical development of its JAK inhibitor candidates, including the availability of data from its ongoing clinical trials, and timing for initiation of planned clinical trials. 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 and in commercialization of products, 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, 2018, 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" 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.

Aclaris Contact

Michael Tung, M.D.
Senior Vice President
Corporate Strategy/Investor Relations
484-329-2140
mtung@aclaristx.com

Media Contact

Lauren Barbiero
646-564-2156
lbarbiero@w2ogroup.com

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