Aclaris Therapeutics Announces First Patient Dosed in a Phase 2 Clinical Trial of ATI-501 Oral Suspension in Patients with Alopecia Totalis and Alopecia Universalis

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WAYNE, Pa., June 26, 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 that the first patient has been dosed in Aclaris' Phase 2 clinical trial of its JAK inhibitor product candidate ATI-501 oral suspension in patients with two forms of Alopecia Areata (AA) known as Alopecia Totalis (AT) and Alopecia Universalis (AU). AA is an autoimmune dermatologic condition typically characterized by patchy non-scarring hair loss on the scalp and body. More severe forms of AA include AT, which is total scalp hair loss, and AU, which is total hair loss on the scalp and body.

This multicenter, randomized study, known as AUAT-201, will evaluate the safety, tolerability and efficacy of ATI-501 oral suspension for the treatment of AU or AT in adult subjects. Aclaris intends to enroll approximately 80 subjects with a clinical diagnosis of stable AU or AT. Enrolled subjects will receive either ATI-501 or placebo for 6 months.

The primary efficacy endpoint is the mean change from baseline in the Severity of Alopecia Tool (SALT) score at Week 24. Secondary and exploratory endpoints include the change from baseline in the Alopecia Density and Extent Score (ALODEX) score and various clinician and patient-reported outcomes.

“This trial is the first step in evaluating the potential clinical benefit of ATI-501 oral suspension in treating patients with the alopecia totalis and alopecia universalis forms of alopecia areata,” 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 AA.”

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 Alopecia Areata

Alopecia areata is an autoimmune disease that results in partial or complete loss of hair on the scalp and body. The scalp is the most commonly affected area, but any hair-bearing site can be affected alone or together with the scalp. Onset of the disease can occur throughout life and affects both women and men. AA can be associated with serious psychological consequences, including anxiety and depression. AA affects up to 2.0% of people globally at some point during their lifetime (i.e. incidence) and up to 0.2% of people are affected at any given time (i.e. prevalence). There are currently no drugs approved by the FDA for the treatment of AA.

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 candidate ATI-501 oral suspension. 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, Aclaris' Quarterly Report on Form 10-Q for the quarter ended March 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 "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.

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

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