Aclaris Therapeutics Completes Phase 1 Clinical Trial of ATI-50001 for the Treatment of Alopecia Universalis and Alopecia Totalis

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MALVERN, Pa., May 05, 2017 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led biotechnology company focused on identifying, developing and commercializing innovative and differentiated therapies to address significant unmet needs in medical and aesthetic dermatology, today announced it has completed a Phase 1 clinical trial of ATI-50001, an investigational oral Janus Kinase (JAK) 1/3 inhibitor.

Aclaris is developing ATI-50001 as a treatment for patients with alopecia areata (AA), including the more severe forms of AA that result in total scalp hair loss, known as alopecia totalis, and total hair loss on the scalp and body, known as alopecia universalis. This Phase 1 cross-over trial was conducted in 12 healthy volunteers at one investigational center in the United States to assess the safety, bioavailability, and pharmacodynamics of ATI-50001.

In the trial, treatment with ATI-50001 capsules was well tolerated, with a safety profile similar to placebo. No clinically significant laboratory abnormalities were observed. These data are consistent with results from an earlier Phase 1 clinical trial in 44 healthy volunteers conducted by Rigel Pharmaceuticals in which the study drug was well tolerated at all doses, with a safety profile similar to placebo.

In addition to this oral formulation of the JAK 1/3 inhibitor, Aclaris also plans to develop a topical formulation, known as ATI-50002, for the treatment of AA, vitiligo, and androgenetic alopecia (AGA). Specifically, Aclaris plans to:

- Initiate a Phase 2 dose ranging trial with ATI-50001 for the treatment of alopecia totalis and alopecia universalis in the second half of 2017;
- Submit an Investigational New Drug application (IND) for ATI-50002 for the treatment of patchy AA in mid-2017;
- Initiate a Phase 2 dose ranging trial of ATI-50002 for the treatment of patchy AA in the second half of 2017; and
- Initiate a Phase 2 trial of ATI-50002 for the treatment of vitiligo in the second half of 2017.

Through exclusive licenses, Aclaris has built an extensive intellectual property estate consisting of selective JAK 1/3 compounds, highly selective JAK 3 compounds, and methods of using JAK inhibitors to treat AA, AGA, and various other hair loss disorders. Aclaris has exclusively licensed a patent portfolio from Columbia University directed to methods of using JAK inhibitors for the treatment of AA, AGA, and other hair loss disorders. This portfolio includes a recently issued U.S. patent and recently allowed U.S. applications directed to methods of treating AA, AGA and other hair loss disorders by administering ruxolitinib, baricitinib or decernotinib, and a recently issued patent in Japan directed to pharmaceutical compositions comprising ruxolitinib or baricitinib for use in treating AA, AGA and other hair loss disorders. Aclaris will continue to prosecute additional intellectual property to protect our interests.

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 U.S. Food and Drug Administration (FDA) for the treatment of AA.

About Aclaris Therapeutics, Inc.
Aclaris Therapeutics, Inc. is a dermatologist-led biotechnology company focused on identifying, developing and commercializing innovative and differentiated therapies to address significant unmet needs in medical and aesthetic dermatology. Aclaris is based in Malvern, Pennsylvania and more information can be found by visiting the 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 the clinical development of Aclaris’ JAK 1/3 inhibitor drug candidates for the treatment of dermatological conditions and Aclaris’ intellectual property strategy. 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, risks associated with maintaining its intellectual property portfolio and other risks and uncertainties that are described in Aclaris’ Annual Report on Form 10-K for the year ended December 31, 2016 and other filings Aclaris makes with the SEC 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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