Aclaris Therapeutics Provides Update on Oral and Topical JAK 1/3 Inhibitor Clinical Trials

December 17, 2018

- Conference call to be held and accompanying slide deck with photos to be included with Current Report on Form 8-K

WAYNE, Pa., Dec. 17, 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 dermatology, both aesthetic and medical, and immunology, today provided updated data from three clinical trials for ATI-502, an investigational topical Janus kinase (JAK) 1/3 inhibitor, an update on the expected release of topline data for one clinical trial for ATI-502, and an enrollment update for a clinical trial for ATI-501, an investigational oral JAK 1/3 inhibitor.

AA-202 Topical and AUATB-201 Topical are ongoing Phase 2 clinical trials of ATI-502 for the treatment of alopecia areata (AA) in the United States and Australia, respectively. In AA-202 Topical, 11 patients with the more severe forms of AA, alopecia universalis (AU) and alopecia totalis (AT), were treated with ATI-502 in an initial double-blind pharmacokinetic and pharmacodynamic study for 28 days before entering a 12-month open-label extension. In AUATB-201 Topical, an open-label clinical trial, 12 patients with eyebrow loss due to AA, including patients with AU or AT, had their eyebrows treated with ATI-502 for 6 months. VITI-201 Topical is an open-label pilot clinical trial of ATI-502 administered twice daily in 34 patients with non-segmental facial vitiligo.

As announced in November, Aclaris completed enrollment of AA-201 Topical, a randomized, double-blinded, parallel-group, placebo-controlled trial to evaluate the safety, efficacy and dose response of two concentrations of ATI-502 for the treatment of AA. This trial enrolled 129 patients with patchy AA, who were randomized to receive either ATI-502 or placebo. The primary efficacy endpoint is the mean change from baseline in the Severity of Alopecia Tool (SALT) score at Week 24. Topline data from the AA-201 Topical trial are now expected in the second quarter of 2019.

In addition, Aclaris announced today that it has completed enrollment of AUAT-201 Oral, a randomized, double-blinded, parallel-group, placebo-controlled trial to evaluate the safety, efficacy and dose response of three concentrations of ATI-501 oral suspension for the treatment of AA. This trial enrolled 87 patients with AA, including AT and AU, who were randomized to receive either ATI-501 or placebo. The primary efficacy endpoint is the mean change from baseline in the SALT score at Week 24. Topline data from the AUAT-201 Oral trial are now expected in the third quarter of 2019.

“AA can be a psychologically devastating disease for which many patients do not have adequate options for treatment. Inhibition of the JAK1 and JAK3 pathways is an emerging therapeutic approach. We continue to advance our development programs for oral and topical formulations of JAK inhibitors with the goal of addressing the full spectrum of disease severity for patients living with AA,” said Dr. David Gordon, Chief Medical Officer of Aclaris.

Aclaris to Host Conference Call

Management will conduct a conference call at 5:00 PM ET today to discuss these updates. The conference call will be webcast live over the Internet and can be accessed on the Events section of the Investors page of the Aclaris website at https://investor.aclaristx.com/events. A replay of the webcast will be archived on the Aclaris website for 30 days following the call. An accompanying slide deck with photos will be included as an exhibit to a Current Report on Form 8-K that Aclaris will furnish to the SEC today.

To participate on the live call, please dial (844) 776-7782 (domestic) or (661) 378-9535 (international), and reference **conference ID 3119988** prior to the start of the call.

About Alopecia Areata

Alopecia areata (AA) is an autoimmune disease characterized by partial or complete loss of hair on the scalp, face or body. The scalp is the most commonly affected area. Onset of AA may occur in childhood and most patients experience onset by age 40. The course of disease is unpredictable and may involve spontaneous hair regrowth and sudden hair loss. Over half of patients with AA experience poor health-related quality of life. The disease can be associated with serious psychological consequences, including anxiety and depression. AA affects up to 1.8% of people in the United States and 2.0% of people globally at some point during their lives.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a dermatologist-led biopharmaceutical company focused on 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.

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 drug candidates, including the timing for initiation and completion of planned clinical trials and the availability of data from these 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, 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 filed for the year ended December 31, 2017, Aclaris' Quarterly Report on Form 10-Q filed earlier for the quarter ended September 30, 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.

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