Aclaris Therapeutics Announces Phase 2 Clinical Trial of ATI-502 Topical in Patients with Alopecia Areata Did Not Meet Endpoints

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- ATI-502 did not achieve statistical superiority at the primary or secondary endpoints due to high rates of disease resolution in vehicle-treated patients

WAYNE, Pa., June 26, 2019 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a physician-led biopharmaceutical company focused on immuno-inflammatory diseases, today announced results from a Phase 2 clinical trial of ATI-502 (AA-201 Topical), an investigational topical Janus Kinase (JAK) 1/3 inhibitor, in patients with alopecia areata (AA). ATI-502 did not achieve statistical superiority at the primary or secondary endpoints due to high rates of disease resolution in vehicle-treated patients.

AA-201 Topical, a Phase 2 randomized, double-blinded, parallel-group, vehicle-controlled trial, evaluated the safety, efficacy, and dose response of two concentrations of ATI-502, 0.12% and 0.46%, on the regrowth of hair in 129 subjects with AA. Subjects applied ATI-502 to their scalp twice daily for 24 weeks.

The primary endpoint was the mean percent change from baseline in the Severity of Alopecia Tool (SALT) score at week 24. Secondary endpoints included change in Alopecia Density and Extent (ALODEX) score and multiple investigator and patient reported outcomes.

ATI-502 was observed to be generally well-tolerated. Adverse events were primarily mild or moderate in severity. No treatment-related serious adverse events were reported.

“We are surprised and extremely disappointed by the results of this Phase 2 trial,” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris. “This is disappointing not only for the company, but also for patients who are living with alopecia areata. We sincerely thank the patients and investigators who participated in this trial. We look forward to advancing our other development programs.”

Company to Host Conference Call

Management will conduct a conference call at 5:00 PM ET today to review the 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 3497800 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 physician-led biopharmaceutical company committed to addressing the needs of people with immuno-inflammatory 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.

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 development of Aclaris’ 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 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.

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