Aclaris Therapeutics Announces Publication of Data from Phase 2 Clinical Trial of A-101 Topical Solution for Treatment of Facial Seborrheic Keratosis

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Publication in *Dermatologic Surgery* Highlights Dose-related Efficacy

MALVERN, Pa., Sept. 19, 2017 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led biopharmaceutical company, today announced that results from a Phase 2 clinical trial evaluating two concentrations (40% and 32.5%) of its drug candidate A-101 for the treatment of facial seborrheic keratosis (SK) lesions have been published in the journal *Dermatologic Surgery*. A-101 is an investigational, proprietary, high-concentration hydrogen peroxide-based topical solution that Aclaris is developing as a potential treatment for SK. In the trial, A-101 achieved statistical significance in clearing SK lesions on the face in a dose-related fashion. A-101 was well tolerated at both concentrations studied. The FDA's Prescription Drug User Fee Act (PDUFA) action date for the New Drug Application (NDA) is December 24, 2017. If approved, A-101 40% would be the first FDA-approved medication for SK.

SK is a common skin condition affecting more than 83 million Americans. It is characterized by non-cancerous lesions varying in color from light tan to dark brown or black. SK lesions may be cosmetically worrisome to patients, particularly when they appear on the face. In a survey of 10 dermatologists evaluating their own SK patients (n=406), 80% of patients had SK lesions on their face or neck.

In the randomized, double-blind, vehicle-controlled Phase 2 trial to evaluate A-101 topical treatment for facial SK lesions, the 40% and 32.5% concentrations were each compared to vehicle (placebo) in a total of 119 patients. Greater magnitude of effect was observed with the A-101 40% concentration than the 32.5% concentration when each was compared to vehicle. At day 106, the target lesion was clear or near clear in 68% of patients in the A-101 40% group, 62% of patients in the A-101 32.5% group, and 5% of patients in the vehicle group. Improvements compared to vehicle were seen after just one treatment, but most patients received a second treatment in accordance with the study protocol.

“These data suggest that A-101 40%, if approved, may be an appealing treatment option for dermatologists and their patients who wish to remove SK lesions in highly visible areas, such as the face, with minimal risk of scarring or hypopigmentation,” said Aclaris Chief Scientific Officer Stuart D. Shanler, M.D.

In the Phase 2 trial, A-101 solution had a favorable safety and tolerability profile at both concentrations. There were no treatment-related adverse events among patients treated with A-101. Local skin reactions were predominantly classified as mild and transient. No patients had scarring or hypopigmentation at the end of the trial.

“Sometimes dermatologists determine that the risk of a poor cosmetic outcome is too great in the risk-benefit equation for treatment of SK,” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris. “We are pleased with the results from this study, which highlight the potential of A-101 40% to meet a significant unmet need for a topical, non-invasive treatment for SK.”

About A-101
A-101 40% topical solution, an investigational drug, is a proprietary, high-concentration hydrogen peroxide formulation for the potential treatment of seborrheic keratosis (SK). It is being developed as a non-invasive, in-office treatment administered by physicians or other health care professionals. A 45% concentration of A-101 is also in clinical development for the treatment of verruca vulgaris (common warts).

About Seborrheic Keratosis
Seborrheic keratosis (SK) is a skin condition that affects more than 83 million Americans and is characterized by non-cancerous lesions varying in color from light tan to dark brown or black. SK lesions range in size from a millimeter to a few centimeters wide and usually have a slightly elevated, waxy, scaly appearance. People with SK may be affected with just one lesion or dozens and often have a family history of SK. SK lesions can appear anywhere on the body, except the palms, soles and mucous membranes, and frequently appear in highly visible locations, such as the face or neck. Though the lesions usually do not cause physical discomfort, SK can adversely affect the appearance and emotional well-being of people who have it. Prevalence of SK increases with advancing age and the majority of patients seeking treatment from dermatologists are between 40 and 70 years of age. Fewer than 10% of people with SK receive treatment, though it is one of the most frequent diagnoses made by dermatologists. Currently, there are no FDA-approved medications for SK, and existing treatment procedures are often painful or invasive and can have undesirable outcomes like scarring or dyspigmentation.

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 medical and aesthetic dermatology. Aclaris is focused on underserved market segments with no FDA-approved medications or where treatment gaps exist. 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 Aclaris’ clinical development and potential regulatory approval for A-101 40%. 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, 2016, Aclaris’ Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, 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.

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