Aclaris Therapeutics Submits Marketing Authorization Application in Europe for A-101 40% Topical Solution as a Novel Treatment for Seborrheic Keratosis

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MALVERN, Pa., Aug. 03, 2017 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led biopharmaceutical 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 submitted a Marketing Authorization Application (MAA) with the Medicines Product Agency (MPA) in Sweden for its product candidate A-101 40% Topical Solution for the treatment of seborrheic keratosis. The MPA will act as the reference member state in this decentralized procedure for review of the MAA for potential marketing approval throughout Europe. If approved, A-101 40% Topical Solution would be available to be commercialized in 16 countries in the European Union.

Seborrheic keratosis (SK) lesions are common, non-cancerous skin lesions which can have a negative physical and emotional impact on patients because they may be perceived as cosmetically unattractive and associated with aging. Existing treatments are often painful, invasive and can have undesirable outcomes such as pigmentary changes or scarring. Fewer than 10% of people [in the United States] with SK lesions currently receive treatment.

Positive results from two pivotal Phase 3 trials – SEBK-301 and SEBK-302 – were reported in late 2016 and provide the clinical basis for this MAA submission. In these trials, A-101 40% Topical Solution (A-101 40%) met all primary and secondary endpoints, achieving clinically and statistically significant clearance of SK lesions. The two trials, which were identical in design and together enrolled 937 patients, evaluated the safety and efficacy of A-101 compared with vehicle (placebo) in patients with four target SK lesions on the face, trunk, and extremities.

“This MAA submission represents a major step toward our goal of delivering a novel, topical treatment to address a significant unmet need in the dermatology market,” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris. “If approved, we believe A-101 will have broad appeal across aesthetic and medical dermatology patients – both men and women.”

About Aclaris Therapeutics, Inc.
Aclaris Therapeutics, Inc. is a dermatologist-led biopharmaceutical company focused on identifying, developing and commercializing innovative and differentiated therapies to address significant unmet needs in medical and aesthetic dermatology. Aclaris is focused on large, 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.

About A-101
A-101 40%, an investigational drug, is a proprietary, high-concentration hydrogen peroxide formulation for the treatment of SK. It is being developed as a non-invasive, in-office treatment administered by physicians or other licensed health care professionals. In clinical trials, patients treated with A-101 40% achieved statistically and clinically significant improvement in clearing SK lesions compared to placebo and with a similar adverse event profile. A-101 40% is designed to work by penetrating into the SK lesion and causing oxidative damage, which can ultimately result in the sloughing of the SK cells. A-101 40% has been the focus of a robust clinical development program in which over 700 patients have been treated with A-101. The 45% concentration of A-101 is also in clinical development for the treatment of common warts (verruca vulgaris).

About Seborrheic Keratosis
Seborrheic keratosis (SK) is a skin condition that affects more than 83 million Americans [and 28 million Europeans] 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 [in the United States] with SK receive treatment, though it is one of the most frequent diagnoses made by dermatologists. There are currently no approved medications for SK [in the United States or Europe], and existing treatment procedures are often painful or invasive and can have undesirable outcomes like scarring or dyspigmentation.

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 regulatory pathway for A-101 40% and its potential broad appeal across aesthetic and medical dermatology patients . 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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