FDA Accepts Aclaris Therapeutics' New Drug Application for Topical Treatment of Seborrheic Keratosis, a Common Skin Condition

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PDUFA target action date of December 24, 2017

MALVERN, Pa., May 09, 2017 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led biotechnology company, today announced that the U.S. Food and Drug Administration has accepted its New Drug Application (NDA) A-101 40% topical solution (A-101 40%), an investigational drug, for the potential treatment of seborrheic keratosis (SK), a common skin condition.

The NDA acceptance by the FDA in its 74-day letter indicates that the application is sufficiently complete to permit a substantive review. The PDUFA target action date for the completion of the FDA's review of the NDA is December 24, 2017. If approved, A-101 40% would be the first FDA-approved topical medication for the treatment of SK.

"The FDA's acceptance of our NDA for A-101 40% is a significant achievement that brings Aclaris one step closer to providing an innovative treatment option for SK patients and the physicians who treat the condition," said Christopher Powala, Chief Operating Officer of Aclaris. "There is a significant need for a non-invasive, topical SK treatment as SK often appears in highly visible locations like the face and neck and can adversely affect patients' emotional well-being."

About A-101
A-101 40% topical solution, an investigational drug, is a proprietary, high-concentration hydrogen peroxide formulation for the treatment of seborrheic keratosis (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 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. There are currently 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 biotechnology 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.

Cautionary Note Regarding Forward-Looking Statements (SK only press releases)

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 A-101 for the treatment of SK. 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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