Aclaris Therapeutics Announces Notice of Allowance for a U.S. Patent Application Covering Lead Candidate A-101 Topical Solution

April 26, 2017 7:01 AM ET

Forthcoming Issuance of a U.S. Patent Application Will Fortify and Broaden Aclaris' Intellectual Property Portfolio Surrounding A-101

MALVERN, Penn., April 26, 2017 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led, biotechnology company focused on defining innovative therapies in medical and aesthetic dermatology, today announced that it has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a patent application covering the formulation and methods of use of A-101 40% topical solution (A-101 40%), an investigational drug, being developed by Aclaris for the treatment of seborrheic keratosis (SK) and A-101 45% topical solution (A-101 45%), an investigational drug, being developed by Aclaris for the treatment of common warts (verruca vulgaris). Aclaris submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for A-101 40% as a treatment for SK in February 2017. In August 2016, Aclaris reported positive data from a Phase 2 trial, WART-201, in which patients treated with A-101 45% achieved statistically significant and clinically meaningful improvement on all primary and secondary endpoints. This newly allowed patent application contains 70 allowed claims and expires in 2035.

"We are extremely pleased with this expansion of the patent estate for A-101," said Dr. Neal Walker, President and Chief Executive Officer of Aclaris. "This allowance expands the breadth of and further validates our A-101 intellectual property portfolio. It covers both the A-101 40% and 45% topical solutions, along with other high concentration hydrogen peroxide formulations and their methods of treating SK and other dermatological conditions which adversely impact how patients look, feel and live."

Aclaris' A-101 patent estate additionally includes other granted U.S. and foreign patents and pending patent applications directed to high concentration topical hydrogen peroxide formulations, methods of use, and applicators, for the alleviation of skin conditions including, among others, SK, common warts, molluscum contagiosum, skin tags (acrochordons), and other dermatological conditions.

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 with a waxy, scaly, slightly elevated appearance that can vary in color from light tan to dark brown or black. SK lesions frequently appear in highly visible locations, such as the face or neck, and can have an adverse physical and emotional impact on people who have them. SK sufferers may be affected with just one lesion or dozens and often have a family history of SK. Prevalence of SK increases with advancing age and over three quarters of patients seeking treatment from dermatologists are aged 40 to 69. SK is one of the most frequent diagnoses made by dermatologists, yet it remains undertreated. There are currently no FDA-approved medications for SK, and existing treatment procedures are often painful, 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 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' A-101 intellectual property portfolio. 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 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.

Contact:
Aclaris Contact
Michael Tung, M.D.
Investor Relations
484-329-2140
mtung@aclaristx.com

Media Contact
Mariann Caprino
TogoRun
917-242-1087
M.Caprino@togorun.com

Aclaris Therapeutics, Inc.