

Aclaris Therapeutics Announces Positive Top-Line Phase 3 Results for A-101 In Treating Seborrheic Keratosis, a Common Undertreated Skin Condition

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- *Pivotal Data Show Topical Treatment Delivered Statistically Significant Results, Meeting All Primary and Secondary Endpoints*
- *Aclaris to Submit New Drug Application to FDA in 1Q17*

Company to Host Conference Call Today at 5:00 PM ET

MALVERN, Pa., Nov. 15, 2016 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led clinical-stage pharmaceutical company focused on defining new standards of care in medical and aesthetic dermatology, today announced that two pivotal Phase 3 trials of its lead product candidate A-101 40% Topical Solution (A-101), a novel treatment for seborrheic keratosis (SK) met all primary and secondary endpoints of each trial, achieving clinically and statistically significant clearance of SK lesions.

The two trials, SEBK-301 and SEBK-302, enrolled 937 patients in total and were conducted at 34 centers in the United States. The trials were identical in design and evaluated the safety and efficacy of A-101 compared to vehicle (placebo) in patients with four target SK lesions on the face, trunk and extremities. Of the 937 patients enrolled, 467 patients received A-101 and 470 patients were administered placebo. Investigators assessed the clearance of SK lesions using the validated four-point Physician Lesion Assessment (PLA) rating scale, which characterizes lesions as either clear (PLA=0), near clear (PLA=1), thin (PLA=2), or thick (PLA=3). Patients in each trial had four target SK lesions, including at least one on the face and at least one on the trunk or extremities. Each lesion received up to two treatments three weeks apart.

Efficacy Results

Overall, results from the combined trials showed 51.3% of lesions treated with A-101 were assessed as clear or near clear (PLA \leq 1) at trial completion versus 7.3% of lesions in the placebo group. Notably, 65.3% of lesions on the face treated with A-101 were assessed as clear or near clear at trial completion versus 10.5% of lesions in the placebo group.

The primary endpoint of both trials was the percentage of patients treated with A-101 who achieved clearance (PLA=0) of all four target SK lesions. In the SEBK-301 trial, 4.0% of patients treated with A-101 achieved clearance of all four target SK lesions (p<0.002); in the SEBK-302 trial, 7.8% of treated patients achieved clearance of all four target SK lesions (p<0.0001). None of the patients administered placebo achieved clearance of all four target SK lesions in either trial.

The secondary endpoint of both trials was the percentage of patients treated with A-101 who achieved clearance (PLA=0) of at least three of the four target SK lesions. In the SEBK-301 trial, 13.5% of patients treated with A-101 achieved clearance of at least three of the four target SK lesions (p<0.0001); in the SEBK-302 trial, 23.0% of treated patients achieved clearance of at least three of the four target SK lesions (p<0.0001). None of the patients treated with placebo achieved this endpoint. Clearance of three out of four target lesions is the primary endpoint that Aclaris has agreed upon with European Union (EU) regulators as a basis for approval. Based on these results, Aclaris plans to submit a Marketing Authorization Application in the EU in mid-2017.

An ancillary endpoint was the mean per-patient percentage of target lesions treated with A-101 who achieved clear or near clear of all target SK lesions (PLA \leq 1). In SEBK-301, 47.5% of patients treated with A-101 achieved clear or near clear versus placebo which was 10.2% (p<0.0001). In SEBK-302, 54.3% of patients treated with A-101 achieved clear or near clear versus placebo which was 4.7% (p<0.0001).

“I see many SK patients who lack confidence in their appearance, especially those who have lesions in visible areas such as the face and neck,” said trial investigator Zoe Draelos, M.D., board-certified dermatologist, fellow of the American

Academy of Dermatology. “For patients who seek to improve their appearance, a treatment that can achieve clearance or near clearance of lesions while delivering a favorable aesthetic result would represent a significant advance in the standard of SK treatment.”

SK lesions are common, non-cancerous skin lesions that impact more than 83 million Americans and frequently appear in highly visible locations such as the face or neck. The lesions are typically characterized by a waxy, scaly, elevated appearance and can vary in color from light tan to dark brown or black. SK lesions can have an adverse physical and emotional impact on patients. Existing treatments are invasive, often painful, or have undesirable outcomes like scarring or dyspigmentation.

“We are extremely pleased by these top-line results,” said Aclaris President and Chief Executive Officer Dr. Neal Walker. “We had a productive pre-NDA meeting with the U.S. Food and Drug Administration earlier this year and look forward to submitting a New Drug Application to the FDA in the first quarter of 2017. We are committed to bringing this important new treatment to patients and their physicians.” If approved, A-101 would be the first FDA-approved topical treatment for SK.

Safety Results

There were no treatment-related serious adverse events among patients treated with A-101. The most common adverse events were nasopharyngitis and sinusitis which were determined to be unrelated to A-101.

Local skin reactions, if present, were predominantly classified as mild. The rates of hypopigmentation, hyperpigmentation, and scarring classified as greater than mild were less than one percent in all groups in both trials.

Additionally, Aclaris announced that initial safety results from an open-label safety trial of A-101 (SEBK-303) were consistent with the SEBK-301 and SEBK-302 trials. The SEBK-303 trial enrolled 147 patients at 10 sites across the United States.

“This safety profile in these trials is compelling since there has been a significant need for an effective, non-invasive SK treatment without long-term pigmentary changes,” said Dr. Walker.

Aclaris plans to present this data at a future medical meeting and also for consideration for publication in a peer-reviewed journal.

Management will conduct a conference call at 5:00 PM ET on November 15, 2016 to discuss these results. The conference will be webcast live over the Internet and can be accessed by logging on to the “Investors” section of the Aclaris Therapeutics website, www.aclaristx.com, prior to the event. A replay of the webcast will be archived on the Company’s 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 21069052 prior to the start of the call.

About A-101

A-101 (40% topical solution) is a proprietary, high-concentration hydrogen peroxide formulation in late-stage development for the treatment of seborrheic keratosis (SK). It is being developed as a non-invasive, in-office therapy, able to be administered by physicians or non-physician health care providers. In clinical trials, A-101 showed statistically and clinically significant results in clearing SK lesions with an adverse event profile similar to placebo. A-101 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 has been the focus of a robust clinical development program in which over 700 patients have been treated with A-101. Aclaris plans to submit a New Drug Application (NDA) for A-101 in the first quarter of 2017. If approved, A-101 would be the first FDA-approved topical treatment for SK. A higher 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 clinical-stage dermatologist-led pharmaceutical 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.

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 commercialization of A-101 for the treatment of SK and common warts. 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, 2015, Aclaris' Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

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