Aclaris Therapeutics' A-101 45% Topical Solution Meets Primary and All Secondary Endpoints in Two Phase 2 Clinical Trials for Common Warts

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- *Highly statistically significant results on all primary and secondary endpoints*
- *Statistical significance seen as early as day 28, after 4 weeks of treatment in WART-203*
- *If approved, A-101 45% would be the first FDA approved treatment for common warts*

MALVERN, Pa., Jan. 08, 2018 (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 positive results from its two Phase 2 clinical trials (WART-202 and WART-203) of A-101 45% topical solution (A-101 45%), an investigational new drug for the treatment of common warts (verruca vulgaris). A-101 45% met all primary and secondary endpoints of each trial, achieving clinically and statistically significant clearance of common warts. A-101 45% is a proprietary high-concentration hydrogen peroxide topical solution being developed as a prescription treatment for common warts.

Both trials evaluated the safety and efficacy of A-101 45% as compared to placebo (vehicle). The two randomized, double-blind, vehicle-controlled trials were designed to understand the effects of dose frequency and to explore additional clinical endpoints that will be further evaluated in a planned Phase 3 development program.

The WART-203 trial evaluated 159 patients who self-administered either A-101 45% or placebo twice weekly through Day 56, for a total of 16 treatments. Each patient had between one and six warts at baseline. The trial achieved its primary endpoint, which was mean change from baseline in the Physician's Wart Assessment (PWA) scale score at Day 56 (Visit 10 or one week after the last treatment). The PWA score is a four-point scale of the investigators' assessment of the severity of a target wart at a particular time point.

- The mean reduction in PWA score at Day 56 on the target warts was 0.87 points in patients who received A-101 45%, compared to a reduction of 0.17 points for the target warts that received placebo, a result that was statistically significant ($p<0.001$).

Secondary endpoints of the WART-203 trial:

- The percentage of all treated warts that were clear (PWA = 0) at Day 56 was 30.20% in patients who received A-101 45%, compared to 9.22% among patients in the placebo group ($p<0.001$).
- The percentage of all treated warts that were clear or near-clear (PWA <= 1) at Day 56 was 45.64% among patients who received A-101 45%, compared to 15.60% among patients in the placebo group ($p<0.001$).
- The proportion of patients achieving target wart clearance at Day 56 was 25.32% among those who received A-101 45%, compared to 2.56% among patients in the placebo group ($p<0.0001$).
- The proportion of patients with all treated wart(s) clear at Day 56, stratified by the baseline number of warts treated (1-6), was 18.99% among those who received A-101 45%, compared to 2.56% among patients in the placebo group ($P=0.001$).

The WART-202 trial evaluated 157 patients who self-administered either A-101 45% or placebo once weekly through Day 56, for a total of 8 treatments. Each patient had between one and four warts at baseline. The trial achieved its primary endpoint, which was mean change from baseline in the PWA score of the target wart at Day 56 (one week after the last treatment).

- The mean reduction in PWA score at Day 56 on the target warts was 0.77 points in patients who received A-101 45%, compared to a reduction of 0.23 points for the target warts that received placebo, a result that was also statistically significant ($p<0.001$).

Secondary endpoints of the WART-202 trial:

- The percentage of all treated warts that were clear at Day 56 was 20.75% in patients who received A-101 45%, compared to 2.94% among patients in the placebo group ($p<0.001$).
- The percentage of all treated warts that were clear or near-clear at Day 56 was 52.83% among patients who received A-101 45%, compared to 13.73% among patients in the placebo group ($p<0.001$).
- The proportion of patients achieving target wart clearance at Day 56 was 15.71% among those who received A-101 45%, compared to 1.37% among patients in the placebo group ($p<0.001$).
- The proportion of patients with all treated wart(s) clear at Day 56, stratified by the baseline number of warts treated (1-4), was 11.43% among those who received A-101 45%, compared to 1.37% among patients in the placebo group ($P=0.01$).

Patients in both of the WART-202 and WART-203 trials are continuing in a 3-month open-label drug-free follow-up evaluation to assess the durability of clinical effect.

Safety Results

- There were no treatment-related serious adverse events among patients treated with A-101 45%.
- A-101 45% was well tolerated through visit 10 (Day 56).

"We are extremely pleased by these results," said Dr. Neal Walker, President and CEO of Aclaris. "This is an important milestone for the A-101 45% wart program, and these data further substantiate the potential clinical utility of our proprietary formulation of A-101 45% topical solution. Based on these results, we plan to meet with the FDA mid-year regarding our Phase 3 program for the treatment of common warts. We expect to initiate our Phase 3 program in the second half of 2018."

About Common Warts
Common warts, also called verruca vulgaris, affect more than 22 million Americans. Prevalence is higher in children than adults. Common warts most often appear on the hands and usually look like skin-colored papules with a rough surface. They result when skin cells are infected by human papillomavirus (HPV) and spread via direct contact or contact with infected surfaces. Though common warts may resolve without treatment, they can persist for years. Over-the-counter topical treatments are first-line therapy for common warts but are marginally effective and slow to work. More than two million patients seek treatment for common warts from healthcare professionals each year, possibly because of social stigma, embarrassment or symptoms such as pain, bleeding, itching and burning. There are currently no FDA-approved prescription medications for warts, and existing treatment procedures are often painful or invasive, can have undesirable outcomes like scarring or dyspigmentation, and often require repeat visits.

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, undertreated 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 of A-101 45% for the treatment of 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, 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, Aclaris' Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, 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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