Aclaris Therapeutics Announces Positive Results in Phase 2 Clinical Trial of A-101 for Treatment of Common Warts

August 18, 2016 7:30 AM ET

45% Concentration A-101 Topical Solution Achieved Primary and Secondary Endpoints

MALVERN, Pa., Aug. 18, 2016 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a clinical-stage specialty pharmaceutical company, today announced positive results from its Phase 2 clinical trial (WART-201), of A-101 Topical solution (A-101) for the treatment of common warts (verruca vulgaris). A-101 is a proprietary formulation of high-concentration hydrogen peroxide currently under development as a prescription treatment for common warts.

WART-201 was a randomized, double-blind, vehicle-controlled, clinical trial designed to evaluate the safety and dose-response of 2 concentrations of A-101 Topical solution, 40% and 45%, compared with placebo (vehicle) in patients with common warts. Ninety-eight patients were enrolled in the study with 90 patients completing eight weekly treatments at six investigational centers within the United States.

In the trial, the 45% concentration of A-101 demonstrated clinically relevant and statistically significant improvement in the mean change in the Physician's Wart Assessment (PWA) score and in complete clearance of common warts. The side effect profile was similar to placebo.

WART-201 Efficacy Results:

- The *primary* endpoint was the mean change from baseline in the PWA score one week after the last treatment. Patients treated with 45% concentration A-101 demonstrated a statistically significant change in PWA score versus placebo (p=0.01).

- The *secondary* endpoints included two responder analyses: the proportion of patients whose target wart was judged to be clear on the PWA scale; and the proportion of patients whose target wart was judged to be either clear or barely evident on the PWA scale.
    - A-101 45% Topical solution achieved statistically significant complete clearance of the target wart one week after the last treatment versus placebo (p=0.02).
    - The proportion of target warts treated with A-101 45% Topical solution achieving a score of clear or barely evident one week after the last treatment was also statistically significant versus placebo (p=0.02).

WART-201 Safety Results:

- A-101 was well-tolerated and local skin reactions (LSR) were primarily mild in severity and similar to placebo. The most frequently reported LSR across treatment groups was mild erythema.

"We are extremely pleased with these results," said Dr. Neal Walker, President & CEO of Aclaris. "This is an important milestone for our A-101 development program and substantiates the clinical value of our proprietary formulation of A-101 Topical solution. Based on these results, we plan to continue the development of the 45% concentration of A-101 as a potential treatment for common warts."

About Common Warts (Verruca Vulgaris)
Warts are benign skin growths which appear when human papillomavirus (HPV) infects the top layer of the skin. On an annual basis, 1.9 million people are diagnosed with common warts and although the warts are generally not harmful and in most cases eventually clear without any medical treatment, they may be painful, aesthetically unattractive, and are contagious. Common warts can be removed with slow-acting, over-the-counter products containing salicylic acid. Cryosurgery is the most frequently used in-office treatment for common warts. No prescription drugs have been approved by the FDA for the treatment of common warts.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage specialty pharmaceutical company focused on identifying, developing, and commercializing innovative and differentiated drugs to address significant unmet needs in dermatology. Aclaris is based in Malvern, Pennsylvania and more information can be found by visiting 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 the clinical development of Aclaris' A-101 drug candidate 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, and other risks and uncertainties that are described in 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 June 30, 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.

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.