Aclaris Therapeutics' A-101 45% Topical Solution Meets Primary and All Secondary Efficacy Endpoints in Pivotal Phase 3 Trial for the Treatment of Common Warts (THWART-2)

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- Highly statistically significant results at the primary endpoint - statistical significance seen as early as Day 29
- Highly statistically significant results on all secondary efficacy endpoints
- WART-302 is the first of two Phase 3 pivotal trials for the NDA
- If approved, A-101 45% Topical Solution would be the first FDA approved prescription treatment for common warts

WAYNE, Pa., Sept. 16, 2019 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a physician-led biopharmaceutical company focused on immuno-inflammatory and dermatological diseases, today announced positive results from its Phase 3 clinical trial, THWART-2 (WART-302), of A-101 45% Topical Solution (A-101 45% Topical Solution), an investigational new drug for the treatment of common warts (verruca vulgaris). A-101 45% Topical Solution met the primary and all secondary efficacy endpoints, achieving clinically and statistically significant clearance of common warts. A-101 45% Topical Solution is a proprietary high-concentration hydrogen peroxide topical solution being developed as a potential prescription treatment for common warts.

THWART-2 is one of two randomized double-blind vehicle-controlled Phase 3 pivotal trials conducted by Aclaris to evaluate A-101 45% Topical Solution as a potential treatment for common warts. Aclaris expects to report data from THWART-1 (WART-301), the second Phase 3 trial during the fourth quarter of 2019. Both trials evaluated the efficacy and safety of A-101 45% Topical Solution as compared to placebo (vehicle). The two randomized, double-blind, vehicle-controlled trials were designed to demonstrate the efficacy and safety of A-101 45% Topical Solution for the potential treatment of common warts when applied by subjects (or the parents/guardians of subjects < 18 years).

In the THWART-2 trial, 502 subjects who had one to six warts at baseline were randomized and self-administered either A-101 45% Topical Solution or vehicle twice a week over 8 weeks, for a total of 16 treatments. The trial achieved its primary endpoint with a high degree of statistical significance ($p<0.0001$), i.e. a higher proportion of subjects treated in the A-101 45% Topical Solution arm versus vehicle had all their identified common warts reported as clear at Day 60. Warts were assessed using the Physician Wart Assessment scale (PWA=0) which is a validated four-point scale of the investigators' assessment of the severity of all treated warts.

In the trial, all secondary efficacy endpoints achieved statistical significance in favor of A-101 45% Topical Solution versus vehicle and are described as follows:

- Complete clearance of all warts at Day 137 (12 weeks after last treatment) ($p=0.0001$)
- Mean per subject percent of treated warts cleared at Day 137 ($p<0.0001$)
- Clearance in subjects with a single baseline wart at Day 60 ($p=0.0006$)
- Time to complete clearance of all warts ($p<0.0001$)

There were no treatment-related serious adverse events (SAEs) in subjects treated with A-101 45% Topical Solution; however, SAEs of intestinal obstruction (in the A-101 45% Topical Solution group) and staghorn renal calculus (vehicle group) were assessed by the investigators as unrelated. Treatment-related application site adverse events (AEs) were reported in 53.4% and 8.4% of the A-101 45% Topical Solution and vehicle groups respectively. In the active arm 2% (5 subjects) of application site events were severe (1 pain, and 4 site pallor). The most common AEs (occurring in more than 5% of subjects) were application site pain, pallor, erythema, pruritus, scabbing and erosion. No subjects withdrew because of AEs.

"There are no FDA approved prescription treatments for common warts and we are excited by these data and look forward to the results of the second pivotal Phase 3 trial, THWART-1 (WART-301)," said Dr. Neal Walker, President and CEO of Aclaris. "This treatment is self-administered twice a week for 8 weeks (a total of 16 applications) and we believe these results will be of interest to partners seeking to commercialize A-101 45% Topical Solution."

About Common Warts

Common warts, also called verruca vulgaris, are skin growths caused by a virus infecting the top layer of the skin. They affect an estimated 22 million Americans each year with a higher incidence in children than adults. Common warts are often skin-colored and feel rough but can be darker and smooth. Symptoms include pain, bleeding, itching, and burning. Common warts are contagious and may interfere with social activities, cause embarrassment, and carry a social stigma. Each year, over 2 million people in the U.S. are diagnosed with common warts during a visit to a health care professional.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a physician-led biopharmaceutical company committed to addressing the needs of people with immuno-inflammatory and dermatological diseases who lack satisfactory treatment options. The company's diverse and multi-stage portfolio includes two FDA-approved medicines, one late-stage investigational medicine, and a pipeline powered by a robust R&D engine exploring protein kinase regulation. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn or Twitter @aclaristx.

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 development of Aclaris' drug candidates, including A-101 45% Topical Solution, and the potential for partnerships for commercializing A-101 45% Topical Solution. 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 and in commercialization of products, 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, 2018, Aclaris Quarterly report on Form 10-Q for the quarter ended June 30, 2019, and other filings Aclaris makes with the U.S. Securities and Exchange Commission from time to time. These documents are available under the "SEC filings" 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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