Aclaris Therapeutics' A-101 45% Topical Solution Meets Primary and All Secondary Efficacy Endpoints in Second Successful Pivotal Phase 3 Clinical Trial for the Treatment of Common Warts (THWART-1)

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If approved, A-101 45% Topical Solution would be the first FDA-approved prescription treatment for common warts

- Highly statistically significant results for the primary efficacy endpoint
- Highly statistically significant results for all secondary efficacy endpoints
- Management to host conference call at 4:30 PM ET today

WAYNE, Pa., Oct. 24, 2019 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a physician-led biopharmaceutical company focused on immuno-inflammatory diseases, today announced positive results from its second Phase 3 clinical trial, THWART-1 (WART-301), of A-101 45% Topical Solution (A-101 45%), an investigational new drug, for the potential treatment of common warts (verruca vulgaris). A-101 45% met the primary and all secondary efficacy endpoints, achieving clinically meaningful and statistically significant clearance of common warts. A-101 45% is a proprietary high-concentration hydrogen peroxide topical solution being developed as a potential prescription treatment for common warts.

THWART-1 is the second of two Phase 3 pivotal trials: THWART-1 and THWART-2 (WART-301 and WART-302, respectively) conducted by Aclaris. The two randomized, double-blind, vehicle-controlled trials were designed to evaluate the efficacy and safety of A-101 45% as compared to placebo (vehicle) for the treatment of common warts when applied by subjects (or the parents/guardians of subjects < 18 years).

The THWART-1 trial randomized 503 subjects who self-administered either A-101 45% or vehicle twice a week over 8 weeks, for a total of 16 treatments. Each subject had one to six common warts at baseline. The trial achieved its primary endpoint with a high degree of statistical significance (p=0.0003), i.e. a higher proportion of subjects treated with A-101 45% versus vehicle had all their identified common warts reported as clear at day 60. Warts were assessed using the Physician Wart Assessment™ scale which is a validated four-point scale of the investigators' assessment of the severity of all treated common warts (PWA=0 means clear). All secondary efficacy endpoints also achieved statistical significance in favor of A-101 45% versus vehicle.

Efficacy results from the THWART-1 and THWART-2 trials for the primary and first two secondary endpoints are summarized in the table below:

	PRIMARY Proportion of subjects whose identified common warts are determined to be clear at day 60 (PWA=0)	**SECONDARY** Proportion of subjects whose identified common warts are determined to be clear at day 137 (PWA=0)	**SECONDARY** Mean per-subject percent of all common warts that are clear at day 137 (PWA=0)
	(%)	(%)	(%)
THWART-1			
A-101 45% (n=254)	15.7%	22.4%	28.6%
VEHICLE (n=249)	5.2%	11.6%	14.5%
p-value	0.0003	0.0024	<0.0001
THWART-2			
A-101 45% (n=251)	13.1%	22.3%	27.7%
VEHICLE (n=251)	3.2%	10%	12.2%
p-value	<0.0001	0.0001	<0.0001

In the THWART-1 trial, the two other secondary efficacy endpoints also achieved statistical significance in favor of A-101 45% Topical Solution versus vehicle and are described as follows:

- Proportion of subjects with a single common wart whose wart is clear at day 60 (p=0.0009); and
- Time for subjects to achieve clearance of all treated common warts (p<0.0001).

In THWART-1, there were no treatment-related serious adverse events (SAEs) in subjects treated with A-101 45%; however, 2 non-related treatment emergent SAEs were reported (an animal bite in the A-101 45% group and a suicide attempt in the vehicle group). The most common adverse events (AEs) occurring in more than 5% of subjects in the A-101 45% group were application site pain, scabbing, erythema, pruritus and erosion. Treatment-related AEs were reported in 52.8% (34.6% mild, 17.3% moderate and 0.8% severe) and 6% of the subjects in the A-101 45% and vehicle groups, respectively. No subjects withdrew because of AEs, but one subject in the A-101 45% group discontinued treatment due to application site erythema and vesicles.

The safety data from THWART-1 trial was comparable to that of the THWART-2 trial, which were previously reported in Aclaris' September 16, 2019 press release.

"These results provide robust clinical evidence for the efficacy and safety of A-101 45% and support its viability as a potential treatment for common warts," said Dr. David Gordon, Chief Medical Officer of Aclaris. "These data will serve as the basis for an NDA filing, and we believe A-101 45% will be of interest to partners seeking to commercialize this drug candidate, which has the potential to be the first FDA-approved prescription treatment for common warts."

Company to Host Conference Call

Management will conduct a conference call at 4:30 PM ET today to review these Phase 3 results and related matters. The conference call will be webcast live over the Internet and can be accessed by logging on to the "Investors" page of the Aclaris Therapeutics website, www.aclaristx.com, prior to the event. A replay of the webcast will be archived on the Aclaris Therapeutics website for 30 days following the call. A slide presentation will accompany the conference call.

To participate on the live call, please dial (844) 776-7782 (domestic) or (661) 378-9535 (international), and reference conference ID 9299384 prior to the start of the call.

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 19 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 patients with immuno-inflammatory diseases who lack satisfactory treatment options. The company's diverse and multi-stage portfolio includes one late-stage investigational drug candidate 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%, the potential NDA filing for A-101 45% and the potential for partnerships for commercializing A-101 45%. 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.

Contact:

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

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