Aclaris Therapeutics Completes Enrollment of Phase 3 Pivotal Trials of A-101 for the Treatment of Seborrheic Keratosis (SK); Provides Update on Clinical Programs

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MALVERN, Pa., July 25, 2016 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a clinical-stage specialty pharmaceutical company, today announced the completion of patient enrollment in its two Phase 3 pivotal clinical trials and its Phase 3 open-label safety trial of its lead candidate, A-101 Topical Solution (A-101) for the treatment of seborrheic keratosis (SK). Aclaris expects to report initial results from each of the three Phase 3 trials in the fourth quarter of 2016.

A-101 is a proprietary high-concentration hydrogen peroxide topical solution with the potential to become the first FDA-approved treatment for SK.

In the two Phase 3 pivotal clinical trials (SEBK-301 and SEBK-302), Aclaris is evaluating the safety and efficacy of A-101 (40% concentration) in subjects with SK on the trunk, extremities, and face. Both multicenter, randomized, double-blind, vehicle-controlled trials are being conducted at 34 investigational centers across the U.S.

Aclaris also completed enrollment of the Phase 3 open-label safety trial (SEBK-303).

Additionally, Aclaris completed the enrollment of its Phase 2 clinical trial (Wart-201) evaluating the safety, tolerability, and dose-response of two concentrations of A-101 (40% and 45%) for the treatment of common warts (verruca vulgaris). Wart-201, which is being conducted at six investigational centers within the United States, is a double-blinded, randomized, and vehicle-controlled trial. Aclaris expects to report initial results from the Wart-201 trial in the third quarter of 2016.

“We are excited to have reached this important milestone for A-101, as it brings us closer to our goal of developing the first non-invasive treatment for SK, a condition for which there are currently no FDA-approved treatments,” said Dr. Stuart Shanler, Chief Scientific Officer of Aclaris. “We look forward to completing the clinical trials for both SK and common warts in the coming months.”

About Seborrheic Keratosis

SK lesions are one of the most common skin tumors, affecting over 83 million people in the United States. SK lesions are often pigmented, have a waxy, scaly, slightly elevated appearance and typically multiple growths are present. While benign, these lesions are often cosmetically disturbing, may become symptomatic (irritated, pruritic [itchy], painful) or may be confused with more serious skin lesions. Currently, SK lesions are treated by cryosurgery, electrosurgery, curettage, or surgical removal. Each of these methods may be painful or can result in pigmentary changes or scarring at the treatment site.

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 SK and for 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 March 31, 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.

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