Aclaris Therapeutics Announces First Patient Dosed in Phase 3 Studies Evaluating A-101 45% in Patients with Common Warts

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WAYNE, Pa., Sept. 24, 2018 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led biopharmaceutical company committed to identifying, developing, and commercializing innovative therapies to address significant unmet needs in aesthetic and medical dermatology and immunology, today announced the initiation of a Phase 3 wart program evaluating A-101 (hydrogen peroxide) topical solution 45% (A-101 45%) in patients with common warts. The program consists of the THWART-1 and THWART-2 pivotal studies and will include a long term safety extension study.

“Common warts are a ubiquitous dermatological complaint and a frequent reason for physician visits. These lesions can be persistent, irritating, uncomfortable, and are associated with a social stigma,” said Dr. David Gordon, Chief Medical Officer of Aclaris. “Additional therapeutic options are needed to safely and effectively manage this skin condition. Based on positive data in our Phase 2 studies in common warts, we look forward to further evaluating A-101 45% in a Phase 3 program.”

THWART-1 and THWART-2 Studies

These Phase 3, multicenter, double-blind, randomized, vehicle-controlled, studies will evaluate the safety and efficacy of A-101 45% topical solution compared with vehicle (placebo) in patients with common warts. Investigators will identify and treat up to 6 common warts with A-101 45% study medication or vehicle. All identified common warts will be treated twice a week for up to 8 weeks for a total of up to 16 treatments, and patients will be followed for 12 weeks post the final treatment. The studies are expected to enroll approximately 1000 patients, ages two years and older.

The primary objective of these studies is to evaluate the effectiveness of A-101 45% compared to vehicle in treating common warts. The secondary objectives of these studies include assessing the duration of response, the onset of action, and the safety of A-101 45%.

About Common Warts

Common warts, also called verruca vulgaris, affect more than 22 million Americans. Prevalence is higher in children than in 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, such as salicylic acid topicals, 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. Existing in-office treatment procedures are often painful or invasive, can have undesirable outcomes like scarring or dyspigmentation, and often require repeat visits.

About A-101 45%

A-101 45% topical solution, an investigational drug for the treatment of common warts, is a proprietary formulation of hydrogen peroxide. It is being developed as a topical, non-invasive treatment for self-administration or administration by a caregiver.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a dermatologist-led biopharmaceutical company committed to identifying, developing, and commercializing innovative therapies to address significant unmet needs in dermatology, both aesthetic and medical, and immunology. Aclaris’ focus on market segments with no FDA-approved medications or where treatment gaps exist has resulted in the first FDA-approved treatment for raised seborrheic keratoses and several clinical programs to develop medications for the potential treatment of common warts, alopecia areata, and vitiligo. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn.

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 its drug candidates, including the timing for initiation of planned clinical trials. 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 the Risk Factors section of Aclaris' Annual Report on Form 10-K filed for the year ended December 31, 2017, Aclaris’ Quarterly Report on Form 10-Q filed earlier for the quarter ended June 30, 2018 and other filings Aclaris makes with the U.S. Securities and Exchange Commission 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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