Phase 3 data in the online Journal of the American Academy of Dermatology show Aclaris' ESKATA™ is safe and effective in treating persons with raised seborrheic keratoses

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WAYNE, Pa., June 12, 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 publication of the two pivotal trials leading to the FDA approval of ESKATA (hydrogen peroxide) topical solution, 40% (w/w), for the treatment of raised seborrheic keratoses (SKs) in a prestigious peer-reviewed dermatology journal, the online *Journal of the American Academy of Dermatology* ahead of print.

The article entitled, “Safety and efficacy of hydrogen peroxide topical solution, 40% (w/w) in patients with seborrheic keratoses: results from two identical, randomized, double-blind, placebo-controlled, Phase 3 studies (A-101-SEBK-301/302),”[1] summarized the pivotal results demonstrating the safety and efficacy of ESKATA in treating raised seborrheic keratoses after one to two treatments.

ESKATA is the first and only FDA-approved topical treatment for raised seborrheic keratoses. It is a proprietary, high-concentration stabilized hydrogen peroxide topical solution designed for in-office application by a healthcare provider.

“We are extremely pleased to have the results of these two pivotal Phase 3 SK trials published in such a prestigious medical journal,” noted Stuart Shanler, M.D., Chief Scientific Officer of Aclaris Therapeutics, Inc. “The primary and secondary efficacy endpoints of our Phase 3 trials were complete clearance of four out of four SKs or three out of four SKs respectively, which are high regulatory marks to achieve. As such, it is important to consider the clinical relevance of exploratory endpoints such as Clear/Near-Clear when analyzing the data in its totality.”

This study was funded by Aclaris Therapeutics, Inc. The full article is available for download at https://www.jaad.org/article/S0190-9622(18)30841-7/fulltext and will appear in a future print edition of the *Journal of the American Academy of Dermatology*.

Important Safety Information and Approved Use

ESKATA can cause serious side effects, including:

- **Eye problems.** Eye problems can happen if ESKATA™ (hydrogen peroxide) topical solution, 40% (w/w) gets into your eyes, including: ulcers or small holes in your eyes, scarring, redness, irritation, eyelid swelling, severe eye pain, and permanent eye injury, including blindness.
- **If ESKATA accidentally gets into your eyes, your healthcare provider will tell you to flush them well with water for 15 to 30 minutes. Your healthcare provider may send you to another healthcare provider if needed.**
- **Local skin reactions.** Skin reactions have happened in and around the treatment area after application of ESKATA. Severe skin reactions can include: breakdown of the outer layer of the skin (erosion), ulcers, blisters and scarring. Tell your healthcare provider if you have any skin reactions during treatment with ESKATA.

The most common side effects of ESKATA include: itching, stinging, crusting, swelling, redness and scaling.

Your healthcare provider will not apply another treatment of ESKATA if your treated area is still irritated from the previous treatment.

Tell your healthcare provider right away if ESKATA gets into your eyes, mouth or nose during application. ESKATA is for topical use on the skin only, and is not for use in your eyes, mouth or vagina.

These are not all the possible side effects of ESKATA.

Approved Use for ESKATA

ESKATA is a prescription medicine used to treat seborrheic keratoses that are raised.

ESKATA is for use as an in-office treatment. ESKATA is applied by your healthcare provider and is not for use at home.

You are encouraged to report negative side effects of prescription drugs to the FDA. Contact Aclaris Therapeutics, Inc. at 1-833-ACLARIS or 1-833-225-2747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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 the commercial use of ESKATA and the expansion of our intellectual property portfolio covering ESKATA. 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 March 31, 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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[1] Baumann LS, Blauvelt A, Draelos ZD, Kempers SE, Lupo MP, Schlessinger J, Smith SR, Wilson DC, Bradshaw M, Estes E, Shanler SD, Safety and efficacy of hydrogen peroxide topical solution, 40% (w/w) in patients with seborrheic keratoses: results from two identical, randomized, double-blind, placebo-controlled, phase 3 studies (A-101-SEBK-301/302), *Journal of the American Academy of Dermatology*(2018; published online June 1, 2018), doi: 10.1016/j.jaad.2018.05.044.

Source: Aclaris Therapeutics, Inc.