Aclaris Therapeutics Receives European Approvals of ESKATA® (hydrogen peroxide) cutaneous solution, 685 mg

February 28, 2019

WAYNE, Pa., Feb. 28, 2019 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a dermatologist-led biopharmaceutical company focused on dermatological and immuno-inflammatory diseases, today announced that it received approval from the Swedish Medical Products Agency to market ESKATA® (hydrogen peroxide) cutaneous solution, 685 mg for the treatment in adults of seborrheic keratoses that are not pedunculated and have up to a maximum diameter of 15 mm each. Aclaris also has received approval to market the medicine in the United Kingdom, Iceland, Belgium, and Finland.

“In its role as the reference member state, Sweden worked with all concerned member states to establish the approvability of the medicine,” said Christopher Powala, Chief Regulatory and Development Officer for Aclaris. “We have submitted marketing authorization applications in ten additional member states within the European Economic Area through the decentralized procedure.”

Aclaris is seeking a commercial partner or partners to market the medicine as an aesthetic skin treatment in various European countries with the brand name ESKATA in Finland, Iceland, Netherlands, Norway, Portugal, Spain, Sweden, Czech Republic, Belgium and the brand name ESKERIELE® in Austria, France, Germany, Ireland, Italy, and the United Kingdom.

About ESKATA

In December 2017, ESKATA® (hydrogen peroxide) topical solution, 40% (w/w) received U.S. Food and Drug Administration (FDA) approval to treat raised seborrheic keratoses, or SKs.

U.S. Important Patient Safety Information

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 in the U.S.

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 Seborrheic Keratoses

Seborrheic keratoses (SKs) are non-cancerous skin growths that are most commonly seen in middle-aged and older adults. SKs vary in color from flesh-colored to pink, yellow, gray, tan, brown, or black; can range in size from a millimeter to a few centimeters wide; and typically have a slightly elevated, waxy or scaly appearance. The number of SKs tends to increase with advancing age. SKs frequently appear in highly visible locations, such as the face or neck, but can also appear anywhere on the body, except the palms, soles and mucous membranes.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a dermatologist-led biopharmaceutical company focused on identifying, developing, and commercializing innovative therapies to address significant unmet needs in aesthetic and medical dermatology 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 marketing approval of ESKATA in other countries, Aclaris' regulatory strategy and ex- U.S. business partnerships. 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 Aclaris' reliance on third parties over which it may not always have full control, risks associated with maintaining its intellectual property portfolio and other risks and uncertainties that are described in Aclaris' Annual Report on Form 10-K for the year ended December 31, 2017, Aclaris' Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 and other filings Aclaris makes with the SEC 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.

Aclaris Therapeutics Contacts

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

Media Contact
Sheila Kennedy
Vice President, Corporate Communications
484-321-5559
media@aclaristx.com

Business Development Contact
Jeffrey Wayne
Vice President, Business Development
(484) 999-4901
jwayne@aclaristx.com

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