Aclaris Therapeutics Closes Acquisition of RHOFADE® (oxymetazoline hydrochloride) cream, 1% from Allergan

December 3, 2018

WAYNE, Pa., Dec. 03, 2018 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a dermatologist-led biopharmaceutical company focused on identifying, developing, and commercializing innovative therapies to address significant unmet patient needs in aesthetic and medical dermatology and immunology, today announced the closing of its acquisition of the worldwide rights to RHOFADE® (oxymetazoline hydrochloride) cream, 1% and additional intellectual property from Allergan Sales, LLC on November 30, 2018. RHOFADE cream was approved by the U.S. Food and Drug Administration (FDA) in 2017 for the topical treatment of persistent facial erythema (redness) associated with rosacea in adults.

Rosacea is a chronic disease characterized by enduring facial redness and/or skin thickening. Other signs of rosacea include facial flushing, visible blood vessels (telangiectasia), blemishes resembling acne (papules and pustules), and eye irritation. Burning or stinging, swelling (edema), and dry appearance may accompany these signs. Persistent facial redness is the single most common sign of rosacea in most skin types and, according to a survey of 1,289 patients with rosacea conducted by the National Rosacea Society, affects 71% of patients with rosacea. Consensus recommendations for the management of rosacea include tailoring therapy to address clinical features.

“An estimated 16 million American adults have rosacea, yet only a small fraction of that number seeks professional care. Further, medications approved for the treatment of the papules and pustules of rosacea have little to no effect on persistent facial redness. We are excited about launching RHOFADE cream with our own team and increasing awareness about this treatment option for persistent facial redness associated with rosacea in adults,” noted Dr. Neal Walker, President and Chief Executive Officer of Aclaris Therapeutics.

In the two pivotal Phase 3 clinical trials conducted by Allergan, once-daily application of RHOFADE cream reduced persistent facial redness associated with rosacea in adults through 12 hours on day 29. The most common adverse reactions for RHOFADE cream were application site dermatitis, worsening inflammatory lesions of rosacea, application site pruritus, application site erythema, and application site pain.

Patients who experience persistent facial redness should talk to their dermatologist about their condition. RHOFADE cream is currently available with a prescription. For more information, please see RHOFADE cream full Prescribing Information at www.aclaristx.com/uploads/ACRS-Rhofade-PI.pdf.

INDICATION
RHOFADE cream 1% is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

IMPORTANT SAFETY INFORMATION AND WARNINGS
WARNINGS AND PRECAUTIONS
Potential Impacts on Cardiovascular Disease
Alpha-adrenergic agonists may impact blood pressure. **RHOFADE** cream should be used with caution in patients with severe or unstable or uncontrolled cardiovascular disease, orthostatic hypotension, and uncontrolled hypertension or hypotension. Advise patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension/hypotension to seek immediate medical care if their condition worsens.

Potentiation of Vascular Insufficiency
RHOFADE cream should be used with caution in patients with cerebral or coronary insufficiency, Raynaud’s phenomenon, thromboangiitis obliterans, scleroderma, or Sjögren’s syndrome. Advise patients to seek immediate medical care if signs and symptoms of potentiation of vascular insufficiency develop.

Risk of Angle Closure Glaucoma
RHOFADE cream may increase the risk of angle closure glaucoma in patients with narrow-angle glaucoma. Advise patients to seek immediate medical care if signs and symptoms of acute angle closure glaucoma develop.

CONTRAINDICATIONS
There are no contraindications for **RHOFADE** cream.

ADVERSE REACTIONS
The most common adverse reactions ≥1% for **RHOFADE** cream were: application-site dermatitis 2%, worsening inflammatory lesions of rosacea 1%, application-site pruritus 1%, application-site erythema 1%, and application-site pain 1%.

For topical use only. Not for oral, ophthalmic, or intravaginal use.

Please see RHOFADE cream full Prescribing Information at www.aclaristx.com/uploads/ACRS-Rhofade-PI.pdf.

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 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' commercialization of RHOFADE cream and the ability to treat persistent facial redness due to rosacea in adults with RHOFADE cream. Forward-looking 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 related to whether Aclaris will be able to commercialize RHOFADE cream successfully 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, 2017, Aclaris' Quarterly Report on Form 10-Q for the quarter ended September 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 "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.

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