Aclaris Therapeutics Announces Issuance of Additional Orange Book Listable Patent Covering RHOFADE® (Oxymetazoline Hydrochloride) Cream, 1%

July 9, 2019

- **Issuance of U.S. Patent No. 10,335,391 Further Strengthens Aclaris' RHOFADE Patent Portfolio**

WAYNE, Pa., July 09, 2019 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a physician-led biopharmaceutical company focused on immuno-inflammatory and dermatological diseases, today announced that the United States Patent and Trademark Office (USPTO) has issued U.S. Patent No. 10,335,391 covering methods of treating facial erythema associated with rosacea using a 1.0% w/w oxymetazoline hydrochloride composition. This issued U.S. Patent will be listed in the Orange Book for RHOFADE and is set to expire in June 2035. RHOFADE is the first α1A adrenoceptor agonist approved for the topical treatment of persistent facial erythema (redness) associated with rosacea in adults, which is estimated to affect nearly 16 million people in the U.S.

The patent contains 37 claims directed to methods of treating facial erythema associated with rosacea. The claimed methods include topically administering once daily on the face of the patient a composition comprising 1.0% w/w oxymetazoline hydrochloride as the sole active ingredient.

The RHOFADE patent estate includes five other Orange Book listed U.S. patents expiring between January 2024 and June 2035, as well as several pending U.S. patent applications. Internationally, RHOFADE is covered by several issued European patents, including European Patent No. EP2675449, granted on April 24, 2019, which is directed to the use of oxymetazoline cream for the topical treatment of inflammatory lesions associated with rosacea. RHOFADE is also covered by issued patents in Japan, South Korea, Australia, and several other major foreign countries.

"Aclaris continues to expand its intellectual property estate and we are pleased to add a 6th Orange Book listable patent to the intellectual property portfolio covering RHOFADE. This U.S. patent, together with the recently granted European patent, augment our strong worldwide intellectual property portfolio covering RHOFADE," said Dr. Neal Walker, President and Chief Executive Officer of Aclaris.

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 physician-led biopharmaceutical company committed to addressing the needs of people with immuno-inflammatory and dermatological diseases who lack satisfactory treatment options. The company's diverse and multi-stage portfolio includes two FDA-approved medicines, one late-stage investigational medicine, and a pipeline powered by a robust R&D engine exploring protein kinase regulation. Aclaris Therapeutics' active development programs focus on areas where significant treatment gaps exist, such as common warts, alopecia areata, and vitiligo. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn or Twitter @aclaristx.

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

beliefs about Aclaris' intellectual property portfolio. 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 for the year ended December 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 "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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