Aclaris Therapeutics Files Patent Infringement Lawsuit Against Taro Pharmaceuticals, Inc. for Filing an ANDA for a Generic Version of RHOFADE® (oxymetazoline hydrochloride) cream, 1%

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WAYNE, Pa., Oct. 08, 2019 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (Nasdaq: ACRS), a physician-led biopharmaceutical company focused on immuno-inflammatory diseases, announced today that the company, together with Allergan, Inc., has filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Taro Pharmaceuticals, Inc. ("Taro"), related to an Abbreviated New Drug Application ("ANDA") that Taro filed with the U.S. Food and Drug Administration ("FDA") to market a generic version of RHOFADE® (oxymetazoline hydrochloride) cream, 1% ("RHOFADE").

The lawsuit claims infringement of U.S. Patent Nos. 7,812,049, 8,420,688, 8,815,929, 9,974,773 and 10,335,391, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for RHOFADE. Aclaris Therapeutics received a Paragraph IV Notice Letter from Taro dated August 28, 2019, advising that Taro had submitted an ANDA to the FDA seeking approval from the FDA to manufacture and market a generic version of RHOFADE prior to the expiration of the Orange Book-listed patents.

Aclaris intends to vigorously enforce its intellectual property rights relating to RHOFADE.

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' intent to vigorously defend its intellectual property. 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 related to the ability of the company to protect its intellectual property and defend its patents and the possible introduction of generic products, 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, Aclaris' Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, 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.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a physician-led biopharmaceutical company committed to addressing the needs of people with immuno-inflammatory diseases who lack satisfactory treatment options. The company's diverse portfolio includes 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. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn or Twitter @aclaristx.

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