Aclaris Therapeutics Submits Investigational New Drug Application for ATI-450, an oral MK2 inhibitor, for the Treatment of Rheumatoid Arthritis

April 25, 2019

WAYNE, Pa., April 25, 2019 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a physician-led biopharmaceutical company focused on immuno-inflammatory and dermatological diseases, today announced that it has submitted an Investigational New Drug (IND) Application to the U.S. Food and Drug Administration (FDA) for ATI-450, an oral MK2 inhibitor, for the treatment of rheumatoid arthritis (RA). If the IND is allowed by the FDA, Aclaris plans to initiate a Phase 1 clinical trial of ATI-450 in the second half of 2019.

"We are very pleased to have this IND under review by the FDA," said Dr. Neal Walker, President & Chief Executive Officer of Aclaris. "We look forward to beginning the development of ATI-450 as a potential treatment for rheumatoid arthritis and other potential indications driven by TNFα, IL-1β, IL-6, or IL-8. We believe there is an important need to provide additional treatment options for rheumatoid arthritis to improve overall patient care."

ATI-450, an investigational medicine formerly known as CDD-450, would be the first novel compound created by Confluence Discovery Technologies, Inc., our indirect wholly owned subsidiary, to enter the clinical phase of development. Aclaris plans to initiate a Phase 1 single ascending dose study of safety, tolerance, and pharmacokinetics followed by several cohorts of multiple ascending doses. Aclaris is actively considering additional indications for clinical testing in the future.

Dosed orally, ATI-450 is a novel, selective MK2 (mitogen-activated protein kinase-activated protein kinase 2; MAPKAPK2) pathway inhibitor. MK2 is a key regulator of pro-inflammatory mediators including TNFα, IL-1β, IL-6, IL-8 and other essential pathogenic signals in chronic inflammatory and autoimmune diseases, as well as in cancer. Selective MK2 pathway inhibitors are being investigated for their potential ability to block inflammatory cytokine production and activity and, thereby, restore balance to the body's immune system. Selective MK2 pathway inhibitors are also being evaluated in cancer models for their ability to block stromal inflammation and affect cell-cycle checkpoint activity. MK2 pathway inhibitors have the potential to treat patients with a variety of inflammatory and autoimmune diseases, as well as cancer. As an oral drug candidate, ATI-450 is being developed as a potential alternative to anti-TNF/anti-IL-1 biologics.

About Rheumatoid Arthritis

RA is the most common form of autoimmune arthritis. It affects more than 1.3 million Americans. About 75% of RA patients are women, and 1–3% of women may get rheumatoid arthritis in their lifetime. The disease most often begins between the ages of 30 and 50, and is a chronic disease which causes joint pain, stiffness, swelling, and decreased movement of the joints. Small joints in the hands and feet are most commonly affected, but RA can affect organs, such as eyes, skin or lungs.

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 expectations regarding the clinical development of ATI-450, including the timing for initiation of planned clinical trials. 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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