Aclaris Therapeutics Completes Enrollment in Phase 2b Study of Oral Zunsemetinib (ATI-450) for Moderate to Severe Rheumatoid Arthritis (ATI-450-RA-202)

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- Topline Data Anticipated in Q4 2023

WAYNE, Pa., June 13, 2023 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases, today announced the completion of enrollment into ATI-450-RA-202, its Phase 2b trial of oral zunsemetinib in patients with moderate to severe rheumatoid arthritis (RA). Aclaris expects to announce top-line efficacy, safety and other preliminary data from this trial in the fourth quarter of this year.

"We are very pleased with the rate of enrollment into this important trial in the development of zunsemetinib for RA, reflecting the commitment and enthusiasm of our investigators, their patients, our partners and our own team," stated Gail Cawkwell, M.D., Ph.D., Aclaris' Chief Medical Officer. "I am particularly encouraged by the low rate of discontinuations in this trial to date, as well as the fact that our data safety monitoring committee, which meets regularly, has not raised any concerns through this point in the trial. We look forward to reporting the top line results in the fourth quarter."

ATI-450-RA-202 is a Phase 2b, randomized, multicenter, double-blind, placebo-controlled, dose-ranging study to investigate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of two doses of zunsemetinib plus methotrexate (MTX) versus placebo plus MTX in patients with moderate to severe RA who have had an inadequate response to MTX alone. The study has enrolled 251 patients across the three treatment arms (ATI-450 20mg BID, ATI-450 50mg BID, Placebo) at over 20 trial sites in the U.S., Poland, Bulgaria and Czech Republic. The primary efficacy endpoint is the proportion of patients achieving an ACR20 response following 12 weeks of treatment. Secondary efficacy endpoints include ACR50 response, ACR70 response, DAS28-CRP and other pertinent RA measures.

About Zunsemetinib (ATI-450)

Zunsemetinib is an investigational oral mitogen-activated protein kinase-activated protein kinase 2 (MK2) inhibitor. This mechanism potentially leads to the inhibition of multiple cytokines, chemokines, matrix metalloproteases and other inflammatory signals. Key inflammatory cytokines driven by this mechanism include TNFα and interleukin-1α, -1β, -6, -8 and -17 (IL1α, IL1β, IL6, IL8 and IL17). Aclaris is developing zunsemetinib as a potential treatment for rheumatoid arthritis and psoriatic arthritis, with potential future opportunities in a variety of other immuno-inflammatory conditions.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates to address the needs of patients with immuno-inflammatory diseases who lack satisfactory treatment options. The company has a multi-stage portfolio of drug candidates powered by a robust R&D engine exploring protein kinase regulation. For additional information, please visit www.aclaristx.com.

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," "intend," "may," "plan," "potential," "will," and similar expressions, and are based on Aclaris' current beliefs and expectations. These forward-looking statements include Aclaris' expectations regarding the timing of reporting results from ATI-450-RA-202 as well the potential future opportunities for the clinical development of zunsemetinib. 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, Aclaris' ability to enter into strategic partnerships on commercially reasonable terms 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, 2022 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" page of the "Investors" section of Aclaris' website at 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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