Aclaris Therapeutics Provides R&D Update

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WAYNE, Pa., Jan. 11, 2022 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases, today provides an update on the status of certain of its clinical programs and on its research and development (R&D) operations.

Clinical Program Update:

- **Zunsemetinib**, an Investigational Oral MK2 Inhibitor
  - Aclaris initiated study activities and began activating sites in December 2021 in the following two studies:
    - **ATI-450-RA-202**: Phase 2b clinical trial of zunsemetinib in subjects with moderate to severe rheumatoid arthritis (RA). This is Aclaris' second Phase 2 clinical trial of zunsemetinib in subjects with moderate to severe RA, and is primarily designed to assess the efficacy of multiple doses of zunsemetinib to aid in the selection of an optimal dose to progress in future development.
    - **ATI-450-HS-201**: Phase 2a clinical trial of zunsemetinib in subjects with moderate to severe hidradenitis suppurative (HS).
- **ATI-2138-PKPD-101**: Aclaris completed dosing of the first cohort of subjects in its Phase 1 single ascending dose clinical trial of ATI-2138, its investigational oral ITK/TXK/JAK3 inhibitor, in healthy subjects, in December 2021. This is Aclaris' first-in-human trial of ATI-2138, and is designed to assess the safety and tolerability of ATI-2138 in healthy subjects and provide dosing guidance for future clinical trials.

R&D Operations Update:

- David Gordon, Aclaris' Chief Medical Officer, left the Company effective January 7, 2022.
- Aclaris has bolstered its R&D group, including in the areas of clinical, preclinical and discovery, quality, pharmacology, and regulatory.
- As Aclaris continues to grow and evolve, the Company plans to hire several key leadership positions over the coming months to support the operational plans and strategic direction of the Company.

"We are very excited to start the new year with the commencement of three clinical trials," said Dr. Neal Walker, President and CEO of Aclaris. "Our clinical data to date demonstrate the potential for zunsemetinib to be a new oral approach for the treatment of RA, and we hope to further this finding in the Phase 2 trials, including in additional indications, and support our hypothesis that MK2 inhibition is an important novel target for the treatment of immuno-inflammatory diseases. The commencement of our first-in-human trial of ATI-2138 is also an important first step in the clinical development of ATI-2138. In addition, as we expand and develop our pipeline, we have and continue to strengthen the breadth and expertise of our R&D group to meet our needs. Lastly, we would like to thank Dave for his contributions to Aclaris and we wish him the best in his future endeavors."

About ATI-450-RA-202

ATI-450-RA-202 is a Phase 2b randomized, multicenter, double-blind, parallel group, placebo-controlled, dose ranging trial to investigate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of multiple doses (20mg and 50mg BID) of zunsemetinib in combination with methotrexate in subjects with moderate to severe RA. This trial will consist of a 12-week treatment period and a 30-day follow-up period, and will seek to enroll subjects in the United States and in multiple countries in Europe. The primary endpoint is the proportion of subjects achieving American College of Rheumatology 20% (ACR20) at week 12.

About ATI-450-HS-201

ATI-450-HS-201 is a Phase 2a randomized, multicenter, double-blind, placebo-controlled trial to investigate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of zunsemetinib (50mg BID) in subjects with moderate to severe HS. This trial will consist of a 12-week treatment period and a 30-day follow-up period, and will seek to enroll subjects in the United States. The primary endpoint is the change in inflammatory nodule and abscess count at week 12.

About Zunsemetinib

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 tumor necrosis factor α (TNFα) and interleukin-1α, -1β, -6 and -8 (IL1α, IL1β, IL6 and IL8). Aclaris is developing zunsemetinib as a potential treatment for RA and other immuno-inflammatory diseases.

About ATI-2138-PKPD-101

ATI-2138-PKPD-101 is a first-in-human Phase 1 randomized, observer-blind, placebo-controlled, single ascending dose trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of ATI-2138 in healthy subjects.

About ATI-2138

ATI-2138 is an investigational oral ITK/TXK/JAK3 (ITJ) inhibitor. The ITJ compound interrupts T cell signaling through the combined inhibition of ITK/TXK/JAK3 pathways in lymphocytes. Aclaris is developing ATI-2138 as a potential treatment for T-cell mediated autoimmune diseases.

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 the clinical development and potential benefits of zunsemetinib as a potential treatment for HS and RA and ATI-2138 as a potential treatment for psoriasis and/or inflammatory bowel disease, and the planned expansion of additional personnel. 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, the uncertainty regarding the COVID-19 pandemic 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, 2020 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.

Aclaris Contact

investors@aclaristx.com

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