



Aclaris Therapeutics Provides 2023 Outlook

January 6, 2023

WAYNE, Pa., Jan. 06, 2023 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases, today is providing a corporate outlook for 2023.

"2023 is setting up to be an incredibly exciting year for Aclaris with several important expected data read-outs for our two lead clinical programs, zunsemetinib (ATI-450) and ATI-1777," stated Douglas Manion, M.D., Aclaris' Chief Executive Officer and President. "In addition to these highly anticipated clinical milestones, we also are eager to progress the development of our earlier stage assets such as ATI-2138 for T cell mediated diseases and ATI-2231 for certain oncology indications," continued Dr. Manion. "Our research and development team also continues to identify and develop novel kinase drug candidates targeting areas of significant unmet need further bolstering our rich clinical development pipeline."

Clinical Development Programs:

- **Zunsemetinib**, an investigational oral small molecule MK2 inhibitor:
Currently being developed as a potential treatment for immuno-inflammatory diseases
 - **Rheumatoid Arthritis (ATI-450-RA-202)**: This Phase 2b dose ranging trial to investigate the efficacy, safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of multiple doses (20 mg and 50 mg twice daily) of zunsemetinib in combination with methotrexate in subjects with moderate to severe rheumatoid arthritis (RA) is ongoing. Aclaris expects topline data in the second half of 2023.
 - **Hidradenitis Suppurativa (ATI-450-HS-201)**: This Phase 2a trial to investigate the efficacy, safety, tolerability, PK and PD of zunsemetinib (50 mg twice daily) over 12 weeks in subjects with moderate to severe hidradenitis suppurativa (HS) has completed enrollment with 95 patients randomized and is ongoing. Aclaris expects topline data in mid-first half of 2023.
 - **Psoriatic Arthritis (ATI-450-PsA-201)**: This Phase 2a trial to investigate the efficacy, safety, tolerability, PK and PD of zunsemetinib (50 mg twice daily) in subjects with moderate to severe psoriatic arthritis (PsA) is ongoing. Aclaris expects topline data by year end 2023.
- **ATI-1777**, an investigational topical "soft" Janus kinase (JAK) 1/3 inhibitor:
Currently being developing as a potential treatment for moderate to severe atopic dermatitis (AD)
 - **Atopic Dermatitis (ATI-1777-AD-202)**: This Phase 2b trial to determine the efficacy, safety, tolerability, and PK of multiple doses and application regimens of ATI-1777 in subjects with moderate to severe AD is ongoing. Aclaris expects topline data mid-year 2023.
- **ATI-2138**, an investigational oral covalent ITK/JAK3 inhibitor:
Currently being developed as a potential treatment for T cell-mediated autoimmune diseases
 - Aclaris has selected ulcerative colitis as the intended first clinical development target for ATI-2138. Aclaris is also exploring additional indications that are relevant to the mechanism of action.
 - Aclaris initiated a Phase 1 MAD trial of ATI-2138 in healthy volunteers in December of 2022. Aclaris expects topline data from the MAD trial in the second half of 2023.

Preclinical Development Program:

- **ATI-2231**, an investigational oral MK2 inhibitor compound:
Currently being explored as a potential treatment for pancreatic cancer and metastatic breast cancer as well as in preventing bone loss in patients with metastatic breast cancer
 - Second MK2 inhibitor generated from Aclaris' proprietary KINect® drug discovery platform and designed to have a long plasma half-life.

- o Aclaris expects an IND to be submitted in 2023.

Upcoming Corporate Presentation

Dr. Manion will provide a corporate overview at the 41st Annual J.P. Morgan Healthcare Conference on Wednesday, January 11, 2023 at 2:15 PM PT/5:15 PM ET. The conference is being held in San Francisco, CA. A copy of Aclaris' corporate presentation will be posted to the Investor's page of the Aclaris corporate website prior to the event.

A webcast of the presentation may be accessed through the "Events" page of the "Investors" section of Aclaris' website, www.aclaristx.com. The webcast will be archived for at least 30 days on the Aclaris website.

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 development of Aclaris' drug candidates, including the timing of its clinical trials, availability of data from those trials, and timing of regulatory filings. 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, 2021 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 Therapeutics Contact:

Robert A. Doody Jr.
Vice President, Investor Relations
484-639-7235
rdoody@aclaristx.com



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