Aclaris Therapeutics Receives Fast Track Designation for Modzatinib (ATI-2138) for Moderate to Severe Lichen Planus (LP)

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WAYNE, Pa., Aug. 06, 2026 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel product candidates for immuno-inflammatory diseases, today announced that the U.S. Food and Drug Administration (the "FDA") has granted Fast Track Designation for modzatinib (ATI-2138) for moderate to severe lichen planus (LP) including oral erosive LP, cutaneous LP, and lichen planopilaris. Aclaris expects to initiate a phased multi-part Phase 2b trial of modzatinib in LP in the fourth quarter of 2026.

Fast Track designation is intended to facilitate the development and expedite the review of investigational therapies that treat serious conditions and fill an unmet medical need. The designation provides for more frequent interactions with the FDA regarding the development plan and clinical trial design, supporting a potentially more efficient path to registration. Fast Track designation also allows for rolling review of a New Drug Application (NDA), meaning completed sections may be submitted and reviewed on an ongoing basis rather than waiting until every section of the NDA is completed before the entire application can be reviewed. Additionally, Fast Track-designated programs may also be eligible for Priority Review if relevant criteria are met. For more information on the Fast Track designation, visit the FDA's official website.

“Lichen planus is a serious, clinically concerning disease with debilitating symptoms that can affect the quality of life of patients suffering from this disorder; unfortunately, there are currently no approved therapies,” said Dr. Jesse Hall, Chief Medical Officer of Aclaris “This is an important milestone for our company; we look forward to more frequent interactions with the FDA as we move modzatinib into a Phase 2b trial later this year.”

About Aclaris Therapeutics, Inc.

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

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 “anticipate,” “believe,” “expect,” “intend,” “may,” “plan,” “potential,” “will,” and similar expressions, and are based on Aclaris’ current beliefs and expectations. These forward-looking statements include expectations regarding the initiation of a Phase 2b trial of modzatinib in LP in the fourth quarter of 2026. 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 risks related to Aclaris’ ability to maintain Fast Track designation for modzatinib for LP and realize the potential benefits associated with such designation, uncertainties inherent in the conduct of preclinical and clinical studies, 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 macroeconomic environment 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, 2025, 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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