Aclaris Therapeutics Initiates Phase 2b Trial of Modzatinib (ATI-2138) in Lichen Planus (LP)

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- Dual Inhibition of ITK and JAK3 Provides Potential for Modzatinib to be the First Mechanistically Complete Oral Therapy for Lichen Planus, an Unaddressed Inflammatory Disease with No Approved Therapeutic Options -

- Unique Mechanism Targets Key Pathways Implicated in LP Pathology, T-cell Receptor Signaling Upstream and Effector Cytokine Signaling Downstream -

WAYNE, Pa., Nov. 16, 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 initiation of its randomized, double-blind, placebo-controlled Phase 2b A**LP**HA trial of modzatinib (ATI-2138) in patients with moderate-to-severe lichen planus (LP); the first cohort to be enrolled will be patients with oral erosive lichen planus (OLP). The U.S. Food and Drug Administration has granted Fast Track Designation for modzatinib for moderate-to-severe LP.

LP is a chronic, CD8 cytotoxic T cell-driven inflammatory disease that can cause painful oral erosions, permanent scarring hair loss, and genital lesions, and is associated with a risk of malignancy in oral LP. Modzatinib is a potential first-in-class oral therapy with a unique mechanism that inhibits both ITK and JAK3, potentially addressing LP at multiple points in its immune pathology. ITK inhibition blocks T-cell receptor signaling upstream, reducing T cell activation, CD8 T cell-mediated cytotoxicity, and inflammatory cytokine production, while JAK3 inhibition blocks downstream cytokine signaling to limit T cell proliferation, activation, and survival.

“We are excited to initiate the A**LP**HA trial, particularly given the unmet medical need in lichen planus and the mechanistic potential for modzatinib in this indication,” said Dr. Jesse Hall, Chief Medical Officer of Aclaris. “Modzatinib has demonstrated activity in multiple non-clinical disease models, including severe alopecia areata, vitiligo, and rheumatoid arthritis, as well as in a Phase 2a trial in atopic dermatitis with rapid and sustained improvements across clinical and patient-reported measures of disease severity, pruritus, and quality of life. This provides support for its continued development across immuno-inflammatory diseases. There are no FDA-approved therapies for people living with this debilitating disease, and we believe that modzatinib has the potential to be the first mechanistically complete oral therapy in this setting.”

The A**LP**HA trial is a randomized, double-blind, placebo-controlled Phase 2b study to assess the efficacy, safety, and tolerability of modzatinib at two dose levels compared with placebo in approximately 100 participants with biopsy-proven, moderate-to-severe LP not adequately controlled with topical therapies. The trial is designed to include three patient cohorts: oral erosive lichen planus, cutaneous lichen planus (CLP), and lichen planopilaris (LPP). The primary endpoints are change from baseline in activity score of the Oral Disease Severity Score (ODSS) at Week 16 (OLP), modified Lichen Planus Area and Severity Index (LPASI) score at Week 16 (CLP), and Lichen Planopilaris Activity Index (LPPAI) score at Week 24 (LPP). A variety of secondary and exploratory endpoints will also be assessed.

Select Upcoming Milestones

- **Modzatinib**: Top line results from the OLP cohort are expected in the second half of 2027.
- **ATI-9494** (ITK/TXK inhibitor): Aclaris expects to file the IND this quarter. The planned Phase 1 clinical program will evaluate single (SAD) and multiple ascending doses (MAD) of ATI-9494 followed by a proof-of-concept portion in an undisclosed indication. The Company expects to initiate the trial in the first quarter of 2027.
- **ATI-052** (anti-TSLP/IL-4Rα bispecific antibody): Following the recent positive primary analysis results from Phase 1b proof-of-concept trials (press release here), Aclaris expects to prioritize the development of this molecule in eosinophilic esophagitis (EoE). The Company intends to initiate the Phase 2b trial of ATI-052 in EoE in the first quarter of 2027.

About Modzatinib (ATI-2138)

Modzatinib is a highly potent and selective novel investigational pharmacologic agent that acts as a dual inhibitor of interleukin-2-inducible T cell kinase (ITK) and Janus kinase 3 (JAK3). ITK regulates T cell receptor signal transduction and inhibition of this kinase can affect T cell differentiation and activation. JAK3 is a key signal transduction kinase that forms a heterodimer with JAK1, modulates JAK1 phosphorylation of signal transducer and activator of transcription 5 (STAT5), and regulates cytokines that signal through the IL-2Rγ_c to affect lymphocyte proliferation and activation. The results observed in preclinical animal models of inflammation and autoimmune diseases, coupled with the favorable safety, pharmacokinetics, and pharmacodynamics profile in healthy human studies and a Phase 2a trial in atopic dermatitis, support the potential for modzatinib to be the first mechanistically complete oral therapy for a variety of immuno-inflammatory disorders.

About Lichen Planus

Lichen planus (LP) is a chronic, immune-mediated inflammatory disease that can affect the mucous membranes, genitalia, skin, nails, and scalp. It is estimated to affect approximately 0.1% to 2% of the global population; up to 40% of patients seek treatment despite no FDA-approved targeted therapeutic interventions. Disease management is currently focused on immunosuppression and topical symptom control. When LP affects the mouth, it can cause painful burning sores, and erosive forms can make eating, drinking, and oral hygiene difficult; there is a malignancy concern with OLP.

Common symptoms of cutaneous LP include severely itchy, flat-topped bumps or scales that often appear on the wrists, ankles, and lower back. LP can also lead to nail changes, scarring and permanent hair loss (lichen planopilaris), and painful genital lesions. Lichen planus can significantly affect a patient's quality of life, with symptoms such as chronic itch, pain, and discomfort contributing to sleep disturbance, emotional distress, anxiety, depression, and limitations in daily activities.

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 its development plans for modzatinib, ATI-052 and ATI-9494, including its plans to evaluate modzatinib in OLP, CLP and LPP and the timing of top line results, the plans for and timing of initiating an EoE trial for ATI-052, and the plans for and timing of filing an IND, initiating a Phase 1 program for ATI-9494, and the potential therapeutic benefits of modzatinib, including the potential for modzatinib to be a mechanistically complete oral therapy for LP and other immuno-inflammatory disorders. 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, risks associated with interim, top line and preliminary data, 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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