



Acrivon Therapeutics Announces Initial Patient Dosing in Phase 1 Trial of ACR-2316, a Novel WEE1/PKMYT1 Inhibitor Designed Using AP3 for Superior Single-Agent Activity

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- First patient dosed two quarters ahead of original timelines in Acrivon Phase 1 study to assess safety and tolerability of ACR-2316
- ACR-2316 was internally discovered and advanced in 15 months from initial lead to Phase 1 trial initiation uniquely enabled by AP3
- ACR-2316 was rationally designed by AP3 to deliver complete tumor regression and pro-apoptotic tumor cell death through potent activation of CDK1, CDK2, and PLK1
- Initial clinical data from the monotherapy Phase 1 dose optimization trial expected in 2H 2025

WATERTOWN, Mass., Oct. 11, 2024 (GLOBE NEWSWIRE) -- Acrivon Therapeutics, Inc. (“Acrivon” or “Acrivon Therapeutics”) (Nasdaq: ACRV), a clinical stage precision medicine company utilizing its Acrivon Predictive Precision Proteomics (AP3) platform for the discovery, design, and development of drug candidates through a mechanistic match to patients whose disease is predicted sensitive to the specific treatment, today announced that the first patient has been dosed in its Phase 1 clinical trial evaluating ACR-2316, the company’s internally discovered, potent, selective WEE1/PKMYT1 inhibitor, designed by AP3 to overcome the limitations of single-target WEE1 and PKMYT1 inhibitors. ACR-2316 is initially being developed in selected solid tumors identified by AP3.

“The rapid advancement of ACR-2316 into the clinic was enabled by the powerful capabilities of our AP3 Interactome which leverages machine learning to integrate all in-house AP3 phosphoproteomic drug profiling data yielding actionable insights with direct application for streamlined drug discovery,” said Peter Blume-Jensen, M.D., Ph.D., chief executive officer, president, and founder of Acrivon. “Dosing of the first patient is an exciting first milestone for this novel, potent agent which we believe has the potential for broad impact across prevalent cancer types with high unmet need. This progress serves as a testament to the unwavering commitment of the outstanding Acrivon team. We look forward to progressing this trial and expect to report initial clinical data in the second half of 2025.”

The Phase 1 monotherapy clinical trial for ACR-2316 is designed to assess the safety and tolerability of ACR-2316. Additional objectives include the determination of the maximal tolerated dose and recommended Phase 2 monotherapy dose, characterization of the pharmacokinetic profile, and preliminary evaluation of anti-tumor activity. Dose optimization will be guided by drug target engagement in alignment with the Food and Drug Administration’s Project Optimus. AP3-based indication finding and OncoSignature development is ongoing.

About Acrivon Therapeutics

Acrivon is a clinical stage biopharmaceutical company developing precision oncology medicines that it matches to patients whose tumors are predicted to be sensitive to each specific medicine by utilizing Acrivon’s proprietary proteomics-based patient responder identification platform, Acrivon Predictive Precision Proteomics, or AP3. The AP3 platform is engineered to measure compound-specific effects on the entire tumor cell protein signaling network and drug-induced resistance mechanisms in an unbiased manner. These distinctive capabilities enable AP3’s direct application for drug design optimization for monotherapy activity, the identification of rational drug combinations, and the creation of drug-specific proprietary OncoSignature companion diagnostics that are used to identify the patients most likely to benefit from Acrivon’s drug candidates. Acrivon is currently advancing its lead candidate, ACR-368 (also known as prexasertib), a selective small molecule inhibitor targeting CHK1 and CHK2 in a potentially registrational Phase 2 trial across multiple tumor types. The company has received Fast Track designation from the Food and Drug Administration, or FDA, for the investigation of ACR-368 as monotherapy based on OncoSignature-predicted sensitivity in patients with platinum-resistant ovarian or endometrial cancer. Acrivon’s ACR-368 OncoSignature test, which has not yet obtained regulatory approval, has been extensively evaluated in preclinical studies, including in two separate, blinded, prospectively-designed studies on pretreatment tumor biopsies collected from past third-party Phase 2 trials in patients with ovarian cancer treated with ACR-368. The FDA has granted Breakthrough Device designation for the ACR-368 OncoSignature assay for the identification of ovarian cancer patients who may benefit from ACR-368 treatment. The company reported positive clinical data for ovarian and endometrial cancers in April 2024, and in September 2024 it reported additional positive clinical data for endometrial cancer, including a confirmed overall response rate of 62.5% (95% C.I. 30.4% - 86.5%) and further validation of its prospective OncoSignature selection of patients predicted sensitive to ACR-368 by showing segregation of responders in OncoSignature-positive versus OncoSignature-negative patients ($p = 0.009$). The median duration of treatment was not yet reached, but the duration on study was 6 months at the time of the data cut.

In addition to ACR-368, Acrivon is also leveraging its proprietary AP3 precision medicine platform for developing its co-crystallography-driven, internally-discovered pipeline programs. These include ACR-2316, the company’s second clinical stage asset, a potent, selective WEE1/PKMYT1 inhibitor designed for superior single-agent activity as demonstrated in preclinical studies against benchmark inhibitors. The company is also progressing internally- developed preclinical programs, including a cell cycle program with an undisclosed target.

Acrivon leverages its AP3 Interactome, a proprietary, computational analytics platform leveraging machine learning for integrated comprehensive analyses across all large, in-house AP3 phosphoproteomic drug profiling data sets to advance its in-house research programs.

Forward-Looking Statements

This press release includes certain disclosures that contain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this press release, including statements regarding our future results of operations or financial condition, preclinical and clinical results, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,”

“plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” or the negative of these words or other similar terms or expressions. Forward-looking statements are based on Acrivon’s current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, risks and uncertainties that are described more fully in the section titled “Risk Factors” in our reports filed with the Securities and Exchange Commission. Forward-looking statements contained in this press release are made as of this date, and Acrivon undertakes no duty to update such information except as required under applicable law.

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