Acrivon Advances ACR-2316, a Potential First-in-Class WEE1/PKMYT1 Inhibitor, into Randomized Dose Expansion in its Ongoing Phase 1/2 Study

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Favorable, differentiated safety profile and durable single-agent clinical activity, including in heavily pretreated subjects with lung cancer remaining on treatment for over a year

Oral weekly regimen (3 days on/4 days off) at 120 mg and 160 mg QD dose levels selected for randomized dose optimization across AP3-informed solid tumor populations

Dose expansion to evaluate biomarker-selected small cell lung cancer (SCLC), squamous non-small cell lung cancer (sqNSCLC), lung adenocarcinoma (adNSCLC), as well as endometrial, cervical, and esophago-gastric junction cancers

WATERTOWN, Mass., Aug. 05, 2026 (GLOBE NEWSWIRE) -- Acrivon Therapeutics, Inc. (“Acrivon” or “Acrivon Therapeutics”) (Nasdaq: ACRV), a clinical stage biotechnology company discovering and developing precision medicines utilizing its proprietary Generative Phosphoproteomics AP3 (Acrivon Predictive Precision Proteomics) platform deployed for rational drug design and predictive clinical development, today announced that ACR-2316 has advanced into the randomized dose expansion portion of its ongoing Phase 1/2 study. The advancement is supported by the differentiated favorable safety profile and clinical activity observed during dose escalation, including tumor shrinkage and partial responses (PRs) with durable clinical benefit in multiple subjects. Acrivon has selected 120 mg and 160 mg administered orally once daily (QD) on a 3d on/4d off weekly schedule for further dose optimization and final dose selection.

"Advancing ACR-2316 into dose expansion is an important milestone for Acrivon, and the exciting initial clinical activity observed represents further clinical validation of our AP3 platform,” said Peter Blume-Jensen, M.D., Ph.D., chief executive officer, president and co-founder of Acrivon. “We rationally designed ACR-2316 using AP3 to overcome the resistance mechanisms that limit efficacy of single-target WEE1 and PKMYT1 inhibition, hence enabling potent tumor cell death. We are highly encouraged by the durable single-agent activity, including tumor shrinkage and PRs, and clinical benefit observed for more than a year in multiple heavily pretreated subjects with lung cancer. These data support our belief that ACR-2316 has the potential to become an important therapy across multiple high unmet need patient populations."

"ACR-2316 has demonstrated a favorable safety profile in dose escalation, with adverse events limited primarily to transient, mechanism-based hematological events, mainly neutropenia, and a notable absence of non-hematological adverse events,” said Mansoor Raza Mirza, M.D., chief medical officer of Acrivon. “This promising differentiated safety profile and initial clinical activity support its rapid advancement into a randomized expansion phase, to establish the dose with the optimal benefit-risk profile to carry into subsequent development."

ACR-2316 Dose Escalation Data and Observations To Date

- Two weekly (3d on / 4d off QD and 2d on / 5d off QD) oral dosing regimens have been established, while a bi-weekly (2d on / 12d off QD) oral dosing regimen was evaluated, but deprioritized.
- A total of 35 subjects received ACR-2316 across 6 dose levels ranging from 30 to 240 mg QD in the two weekly oral dosing schedules.
- Amongst the subjects treated with ACR-2316 at ≥120 mg QD in the weekly schedules, tumor shrinkage with long-lasting clinical benefit were observed across multiple tumor types, including PRs in lung cancer and endometrial cancer.
- In the 7 efficacy-evaluable subjects (median 3 prior lines of systemic therapy) with SCLC, sqNSCLC, and adNSCLC, AP3-predicted tumor types not previously shown to be sensitive to clinical single agent WEE1 or PKMYT1 inhibitors, a disease control rate of 86% (2 PRs, 4 SD, and 1 PD) was observed.
- Ongoing durable clinical benefit observed in 3 heavily pretreated lung cancer subjects remaining on treatment for over one year.
- In the selected 3d on / 4d off dosing regimen, the 120 mg QD and 160 mg QD doses were well tolerated, with a favorable, differentiated safety profile; no grade ≥4 treatment-related adverse events (TRAEs) were reported, and grade 3 TRAEs were limited to primarily transient, mechanism-based hematologic events, predominantly neutropenia.
- These observations support further evaluation of ACR-2316 in the selected 3d on / 4d off QD regimen in a randomized dose expansion study of AP3-informed tumor types.

The dose expansion will evaluate ACR-2316 in subjects with SCLC, sqNSCLC and adNSCLC, as well as endometrial cancer, cervical cancer, and esophago-gastric junction carcinoma, all with AP3-identified biomarker signatures associated with pathway vulnerability, including loss or mutation of

TP53 or FBXW7, or overexpression or amplification of CCNE1 or CCNB1, or HPV+ in the case of cervical cancer. The expansion utilizes a 3d on / 4d off weekly administration schedule and will include stratification by lung cancer versus non-lung cancer tumor types, with 1:1 randomization within each group to the 120 mg QD or 160 mg QD dose level. The two selected doses are candidate doses for final recommended phase 2 dose selection.

The ACR-2316 dose escalation and expansion study adheres to the principles of the FDA's Project Optimus, which emphasize dose selection based on the totality of efficacy, safety, tolerability, pharmacokinetic and pharmacodynamic data, and specifically stipulate randomized evaluation of multiple doses rather than routine selection of the maximum tolerated dose. Acrivon expects to provide further updates as the study progresses.

About Acrivon Therapeutics
Acrivon is a clinical stage biopharmaceutical company discovering and developing precision medicines utilizing its proprietary Generative Phosphoproteomics AP3 platform. The platform allows the company to interpret and quantify compound specific, drug-regulated pathway activity levels inside the intact cell in an unbiased manner, yielding terabytes of proprietary data and delivering rapid, actionable insights. The AP3 platform is comprised of a growing suite of powerful, internally-developed tools, including the AP3 Data Portal, converting multimodal data into structured data for generative AI analyses, the AP3 Kinase Substrate Relationship Predictor and the AP3 Interactome. These distinctive capabilities enable the company to go beyond the limitations of traditional drug discovery, as well as current AI-based target-centric drug discovery and rapidly design highly differentiated compounds with desirable pathway effects through intracellular protein network analyses and advance these agents into the clinic for streamlined development.

Acrivon is currently advancing its lead program, ACR-368 (also known as prexasertib), a selective small molecule inhibitor targeting CHK1 and CHK2 in a potentially registrational Phase 2 trial for endometrial cancer. The company has received Fast Track designation from the Food and Drug Administration, or FDA, for the investigation of ACR-368 as a monotherapy based on OncoSignature-predicted sensitivity in patients with endometrial cancer. The FDA has granted a Breakthrough Device designation for the ACR-368 OncoSignature assay for the identification of patients with endometrial cancer who may benefit from ACR-368 treatment.

In addition to ACR-368, Acrivon is also leveraging its proprietary Generative AI-driven Phosphoproteomics AP3 platform for developing its co-crystallography-driven, internally discovered pipeline programs. These include ACR-2316, a novel, potent, selective WEE1/PKMYT1 inhibitor designed for superior single-agent activity. The Phase 1/2 trial of ACR-2316 is advancing in an oral weekly dose expansion study. Initial data has shown a highly differentiated, favorable safety profile primarily limited to only transient, mechanism-based hematological adverse events, predominantly only neutropenia. Clinical activity has been observed across multiple tumor types, including SCLC, squamous NSCLC and lung adenocarcinoma, tumor types not shown sensitive to current single agent WEE1 or PKMYT1 inhibitors. Durable clinical activity has been observed, with certain lung cancer subjects remaining on treatment more than one year.

In addition, the company is in early IND-enabling studies with several potential first-in-class development candidates targeting CDK11.

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, 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.

Acrivon intends to use its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD. For more information, please visit www.acrivon.com.

Investor and Media Contacts:
Adam D. Levy, Ph.D., M.B.A.
alevy@acrivon.com

Alexandra Santos
asantos@wheelhouselsa.com