Acrivon Therapeutics Announces FDA has Granted Breakthrough Device Designation for ACR-368 OncoSignature Assay for Endometrial Cancer

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The ACR-368-tailored OncoSignature assay is being used to predict patients most likely to respond to ACR-368 in Acrivon's ongoing, registrational-intent, multicenter Phase 2b trial of ACR-368 in patients with endometrial cancer and other tumor types

Clinical data presented at ESMO 2024 demonstrates statistically significant segregation of patient responders in biomarker-positive versus biomarker-negative subgroups based on prospective OncoSignature patient selection (p-value = 0.009)

Drug-tailored, proprietary OncoSignature biomarker assays are developed using the generative AI-driven Acrivon Predictive Precision Proteomics (AP3) platform, which is also used for streamlined, biologically rational drug design and indication finding

WATERTOWN, Mass., Feb. 05, 2025 (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, announced the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device designation for the ACR-368 OncoSignature assay, a multiplex immunofluorescence assay for the identification of endometrial cancer patients who may benefit from ACR-368 treatment. The designation reflects the FDA's determination that the device is reasonably expected to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions.

"We are pleased that the FDA has designated our ACR-368 OncoSignature assay, developed specifically to prospectively predict tumor sensitivity to ACR-368 and used in our advancing registrational-intent clinical study, as a Breakthrough Device for patients with endometrial cancer," said Peter Blume-Jensen, M.D., Ph.D., chief executive officer, president, and founder of Acrivon Therapeutics. "This is the second such designation for our ACR-368 OncoSignature assay and represents yet another powerful validation of our generative AI-driven AP3 platform. The enrollment and dosing continues for both ACR-368 in our ongoing Phase 2b trials, as well as for ACR-2316, our internally-developed Phase 1 asset, which is a novel, differentiated WEE1/PKMYT1 inhibitor uniquely enabled by AP3. We have now completed enrollment in the first two dose-escalation cohorts of the ACR-2316 Phase 1 trial and initiated dosing in the third cohort."

A company-sponsored, blinded, third-party KOL market research study showed strong interest in the emerging clinical profile of ACR-368. There is an estimated ~30,000 (and growing) new cases of high-grade, locally advanced or metastatic, recurrent (progressed on anti-PD-1 and chemotherapy) endometrial cancer per year in the U.S. The company presented positive clinical data at ESMO 2024 demonstrating a confirmed overall response rate (ORR) of 62.5% (95% CI, 30.4-86.5), as well as prospective ACR-368 OncoSignature patient selection (p = 0.009) in endometrial cancer.

The Breakthrough Devices Program is intended to provide patients and health care providers with timely access to medical devices by speeding up development, assessment, and review for premarket approval, 510(k) clearance, and marketing authorization.

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 generative AI-driven 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 yielding terabytes of high resolution proprietary quantitative data for pathway-based drug design, indication finding, and response prediction. These distinctive capabilities enable AP3's direct application for streamlined rational drug discovery 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 designations for the ACR-368 OncoSignature assay for the identification of patients with endometrial cancer or for patients with ovarian cancer, 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% CI, 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 novel, potent, selective WEE1/PKMYT1 inhibitor designed for superior single-agent activity through strong activation of not only CDK1 and CDK2, but also of PLK1 to drive pro-apoptotic cell death, as demonstrated in preclinical studies against benchmark inhibitors. In addition, the company has a preclinical cell cycle program with an undisclosed target.

Acrivon has developed AP3 Interactome, a proprietary, computational analytics platform driven by 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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