Acrivon Therapeutics Announces FDA Grants Fast Track Designation for Development of ACR-368 in Platinum-Resistant Ovarian Cancer and Endometrial Cancer

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- In previous Phase 2 clinical trials involving more than 400 patients, ACR-368 produced deep, durable monotherapy responses, including complete responses, in a proportion of patients with solid tumors, including platinum-resistant ovarian cancer

-Previous blinded, prospectively-designed studies have demonstrated that the ACR-368 OncoSignature test is able to enrich for responders in two separate pretreatment tumor biopsy studies in patients with ovarian cancer previously treated with ACR-368 and in endometrial cancer patient-derived xenograft models

WATERTOWN, Mass., May 09, 2023 (GLOBE NEWSWIRE) -- Acrivon Therapeutics, Inc. (“Acrivon” or “Acrivon Therapeutics”) (Nasdaq: ACRV), 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 its proprietary proteomics-based patient responder identification platform, today announced that the company has been granted two Fast Track designations by the U.S. Food and Drug Administration (FDA) for the development of ACR-368 in platinum-resistant ovarian cancer and endometrial cancer. Fast Track designation is intended to facilitate the development and expedite the review of promising investigational drugs to treat serious conditions with significant unmet medical needs. A drug candidate that receives Fast Track designation can be eligible for Accelerated Approval and Priority Review, and often have the opportunity to communicate more frequently with the FDA on trial design and data, among other benefits if relevant criteria are met.

One Fast Track development program designation was granted for the investigation of ACR-368 as a monotherapy treatment for patients with OncoSignature® positive, locally advanced, or metastatic, recurrent platinum-resistant high-grade ovarian carcinoma who have received at least one prior systemic treatment regimen. The second Fast Track development program designation was granted for the investigation of ACR-368 as a monotherapy treatment for patients with OncoSignature positive, recurrent high-grade endometrial cancer who have received at least two prior systemic treatment regimens.

ACR-368, also known as prexasertib, is a targeted DNA damage response inhibitor therapy. ACR-368 is being studied in a multicenter, open-label Phase 2 clinical trial with single-arm, potentially registrational cohorts of patients with platinum-resistant ovarian cancer, endometrial adenocarcinoma, and urothelial cancers based on OncoSignature-predicted sensitivity to ACR-368. The OncoSignature test is a first-of-its-kind drug-specific companion diagnostic that uses proteomic biomarkers to identify the patients most likely to benefit from a drug candidate. OncoSignature tests are developed using Acrivon’s Predictive Precision Proteomics (AP3) platform, which matches the drug mechanism of action with the critical tumor-driving pathways.

“We are pleased that the FDA has granted the ACR-368 development program Fast Track designation in recognition of its potential to improve outcomes for patients with OncoSignature-positive platinum-resistant ovarian cancer and endometrial cancer,” said Peter Blume-Jensen, M.D., Ph.D., chief executive officer, president, and founder of Acrivon. “There is a significant unmet need for new treatments for the tumor types we are evaluating in our ongoing Phase 2 trial with ACR-368 and for which we have received Fast Track designation. The overall five-year survival rate is approximately 30% for patients with metastatic ovarian cancer, and less than 20% for patients with metastatic endometrial cancer. By being able to test whether a patient’s disease is likely to be sensitive to the drug’s mechanism of action, we can increase the potential for efficiently halting or reversing the course of the disease. Our approach to drug development is founded in this goal, and we have shown that the ACR-368 OncoSignature test was able to predict drug responders in blinded, prospectively designed studies on pretreatment tumor biopsies collected from past clinical trials and in patient derived xenograft studies. We look forward to continuing this important work and to collaborating with the FDA on the advancement of ACR-368.”

About ACR-368 and ACR-368 Phase 2 Study
ACR-368 is a potent, selective inhibitor of CHK1 and CHK2 which has shown deep, durable single-agent activity, including complete responses, in a proportion of patients across several Phase 2 studies, including platinum-resistant ovarian cancer, squamous cell cancer of the head and neck, as well as anal cancer for which Orphan Drug Designation has been granted. ACR-368 has shown excellent pharmacokinetic and pharmacological properties and a favorable safety profile at the recommended Phase 2 dose across monotherapy studies. Acrivon is advancing ACR-368 in a multicenter, open-label Phase 2 clinical trial with single-arm, potentially registrational cohorts of patients with platinum-resistant ovarian cancer, endometrial adenocarcinoma, and urothelial cancers based on predicted sensitivity to ACR-368. Using the company’s proprietary OncoSignature ®-predictive test, patients who test positive for predicted sensitivity to ACR-368 are administered the recommended Phase 2 dose of ACR-368 (105 mg/m^2) as a monotherapy and will be primarily assessed for evidence of anti-tumor activity (overall response rate). ACR-368 has been granted Fast Track development program designation by the FDA as a monotherapy in OncoSignature-positive patients with platinum-resistant ovarian cancer and endometrial cancer. Patients who are negative on the OncoSignature test may be enrolled in an exploratory single-arm Phase 1b/2 study of the combination of the recommended Phase 2 dose of ACR-368 with low-dose gemcitabine for each of the three cancers. Acrivon has obtained exclusive, world-wide rights to develop and commercialize ACR-368 (also known as prexasertib) under a license agreement with Eli Lilly and Company.

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 enables 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, a selective small molecule inhibitor targeting CHK1 and CHK2 in a potentially registrational Phase 2 trial across multiple tumor types. 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. In addition to ACR-368, Acrivon is also leveraging its proprietary AP3 precision medicine platform for developing its internally-discovered preclinical stage pipeline programs targeting two critical nodes in the DNA Damage Response, or DDR, including WEE1, a protein serine/threonine kinase, and the closely related PKMYT1.

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.

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