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

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The ACR-368-tailored OncoSignature assay is being used in Acrivon's ongoing registrational-intent Phase 2 trial to predict patients most likely to respond to the CHK1/2 inhibitor ACR-368 in three tumor types

Drug-tailored, proprietary OncoSignature assays are developed using the Acrivon Predictive Precision Proteomics (AP3) platform which is also used more broadly to uncover resistance mechanisms and rational drug combinations, and for biological rational drug design for Acrivon's drug candidates

WATERTOWN, Mass., Nov. 28, 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, Acrivon Predictive Precision Proteomics or AP3, 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 ovarian cancer patients who may benefit from ACR-368 treatment. The designation reflects 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 our ACR-368 OncoSignature assay, developed specifically to predict tumor sensitivity to ACR-368 and used in our ongoing registrational-intent clinical study to treat patients based on OncoSignature-predicted sensitivity, has been designated by the FDA as a Breakthrough Device," said Peter Blume-Jensen, M.D., Ph.D., chief executive officer, president, and founder of Acrivon Therapeutics. "It is exclusively through our proprietary AP3 platform that we are able to develop these proteomic-based assays that are designed to predict the patients most likely to benefit from treatment with our drug candidates. We believe this designation is the first of its kind for such an assay, and represents yet another powerful validation of our AP3 platform. The designation importantly also highlights meaningful potential value to patients as we continue to progress ACR-368 in the clinic."

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.

Acrivon has partnered with Akoya Biosciences to co-develop, validate, and commercialize Acrivon's ACR-368 OncoSignature assay.

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, 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. In addition to ACR-368, Acrivon is also leveraging its proprietary AP3 precision medicine platform for developing its internally-discovered preclinical stage pipeline programs, consisting of its development candidate, ACR-2316, a selective, dual WEE1/PKMYT1 inhibitor, and additional programs targeting these two critical nodes in the DNA Damage Response, or DDR, pathways.

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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