Arvinas Announces Submission of New Drug Application to U.S. FDA for Vepdegestrant for Patients with ESR1-Mutated ER+/HER2- Advanced or Metastatic Breast Cancer

June 6, 2025

– This submission is supported by the pivotal Phase 3 VERITAC-2 clinical trial, results of which were recently presented at the 2025 American Society for Clinical Oncology Annual Meeting and published in The New England Journal of Medicine –

– VERITAC-2 data support vepdegestrant as a potential treatment option in patients with ESR1m ER+/HER2- advanced or metastatic breast cancer –

NEW HAVEN, Conn., June 06, 2025 (GLOBE NEWSWIRE) -- Arvinas, Inc. (Nasdaq: ARVN), today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) with its partner Pfizer Inc. (NYSE: PFE), for vepdegestrant for the treatment of patients with ER-positive (ER+)/human epidermal growth factor receptor 2 (HER2)-negative (ER+/HER2-) ESR1-mutated advanced or metastatic breast cancer previously treated with endocrine-based therapy. This submission is based on results from VERITAC-2 (NCT05654623), a global, randomized Phase 3 trial evaluating vepdegestrant versus fulvestrant.

“This milestone comes after an exciting presentation at the American Society of Clinical Oncology’s annual meeting,” said John Houston, Ph.D., Chairperson, Chief Executive Officer and President at Arvinas. “We look forward to the NDA review and to the first ever FDA-approved PROTAC ER degrader potentially being available to patients who could benefit from a much needed, new treatment option.”

Vepdegestrant is being jointly developed by Arvinas and Pfizer for the treatment of patients with advanced or metastatic ER+/HER2- breast cancer and was granted fast track designation as a monotherapy by the FDA. Results from the VERITAC-2 study were recently presented in a late-breaking oral presentation at the American Society of Clinical Oncology (ASCO) 2025 Annual Meeting and were selected for the ASCO press briefing and for Best of ASCO. Detailed results were also simultaneously published in the New England Journal of Medicine.

About the VERITAC-2 Clinical Trial
The Phase 3 VERITAC-2 clinical trial (NCT05654623) is a global, randomized trial evaluating the efficacy and safety of vepdegestrant (ARV-471) as a monotherapy compared to fulvestrant in patients with ER+/HER2- advanced or metastatic breast cancer. The trial enrolled 624 patients at sites in 25 countries who had previously received treatment with a CDK4/6 inhibitor plus endocrine therapy.

Patients were randomized 1:1 to receive either vepdegestrant once daily, orally on a 28-day continuous dosing schedule, or fulvestrant, administered intramuscularly on Days 1 and 15 of Cycle 1 and then on Day 1 of each 28-day cycle starting from Day 1 of Cycle 2. In the trial, 43% of patients (n=270) had ESR1 mutations detected. The primary endpoint was progression-free survival (PFS) in the ESR1-mutation and intent-to-treat populations as determined by blinded independent central review. Overall survival is the key secondary endpoint.

About Vepdegestrant
Vepdegestrant is an investigational, orally bioavailable PROTAC (PROteolysis TArgeting Chimera) protein degrader designed to specifically target and degrade the estrogen receptor (ER). Vepdegestrant is being developed as a potential monotherapy for ER+/HER2- advanced or metastatic breast cancer with estrogen receptor 1 (ESR1) mutations in the second line-plus setting.

In July 2021, Arvinas announced a global collaboration with Pfizer for the co-development and co-commercialization of vepdegestrant; Arvinas and Pfizer will share worldwide development costs, commercialization expenses, and profits.

The U.S. Food and Drug Administration (FDA) has granted vepdegestrant Fast Track designation as a monotherapy in the treatment of adults with ER+/HER2- advanced or metastatic breast cancer previously treated with endocrine-based therapy.

About Arvinas
Arvinas (Nasdaq: ARVN) is a clinical-stage biotechnology company dedicated to improving the lives of patients suffering from debilitating and life-threatening diseases. Through its PROTAC (PROteolysis TArgeting Chimera) protein degrader platform, the Company is pioneering the development of protein degradation therapies designed to harness the body’s natural protein disposal system to selectively and efficiently degrade and remove disease-causing proteins. Arvinas is currently progressing multiple investigational drugs through clinical development programs, including vepdegestrant, targeting the estrogen receptor for patients with locally advanced or metastatic ER+/HER2- breast cancer; ARV-393, targeting BCL6 for relapsed/refractory non-Hodgkin Lymphoma; and ARV-102, targeting LRRK2 for neurodegenerative disorders. Arvinas is headquartered in New Haven, Connecticut. For more information about Arvinas, visit www.arvinas.com and connect on LinkedIn and X.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties, including statements regarding: the NDA review and to the first ever FDA-approved PROTAC ER degrader potentially being available to patients who could benefit from a much needed, new treatment option; and vepdegestrant's development as a potential monotherapy for ER+/HER2- advanced or metastatic breast cancer with ESR1 mutations in the second line-plus setting. All statements, other than statements of historical fact, contained in this press release, including statements regarding Arvinas' strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "goal," "potential," "will," "would," "could," "should," "look forward," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Arvinas may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on such forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements Arvinas makes as a result of various risks and uncertainties, including but not limited to: whether Arvinas and Pfizer will successfully perform their respective obligations under the collaboration between Arvinas and Pfizer; whether Arvinas and Pfizer will be able to successfully conduct and complete clinical development for vepdegestrant as a monotherapy; whether the VERITAC-2 clinical trial will meet the secondary endpoint for overall survival; risks related to our expectations regarding the potential clinical benefit of vepdegestrant to patients; uncertainties relating to regulatory applications and related filing and approval timelines, including the New Drug Application seeking FDA approval of vepdegestrant and the risk that any regulatory approvals, if granted, may be subject to significant limitations on use or subject to withdrawal or other adverse actions by the applicable regulatory authority; whether FDA or other regulatory authorities will require additional information or further studies, or may fail or refuse to approve or may delay approval of vepdegestrant; whether Arvinas and Pfizer, as appropriate, will be able to obtain marketing approval for and commercialize vepdegestrant and other product candidates on current timelines or at all; Arvinas' ability to protect its intellectual property portfolio; Arvinas' reliance on third parties; whether Arvinas will be able to raise capital when needed; whether Arvinas' cash and cash equivalent resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; and other important factors discussed in the "Risk Factors" section of Arvinas' Annual Report on Form 10-K for the year ended December 31, 2024 and subsequent other reports on file with the U.S. Securities and Exchange Commission. The forward-looking statements contained in this press release reflect Arvinas' current views with respect to future events, and Arvinas assumes no obligation to update any forward-looking statements, except as required by applicable law. These forward-looking statements should not be relied upon as representing Arvinas' views as of any date subsequent to the date of this release.

Contacts
Investors:
Jeff Boyle
+1 (347) 247-5089
Jeff.Boyle@arvinas.com

Media:
Kirsten Owens
+1 (203) 584-0307
Kirsten.Owens@arvinas.com