



Arvinas Announces FDA Acceptance of the New Drug Application for Vepdegestrant for the Treatment of ESR1m, ER+/HER2- Advanced Breast Cancer

August 8, 2025

- Filing based on pivotal Phase 3 VERITAC-2 clinical trial demonstrating statistically significant and clinically meaningful improvement in median progression-free survival versus fulvestrant –
- Vepdegestrant is the first PROteolysis TArgeting Chimera (PROTAC) to demonstrate clinical benefit in patients with breast cancer –

NEW HAVEN, Conn., Aug. 08, 2025 (GLOBE NEWSWIRE) -- Arvinas, Inc. (Nasdaq: ARVN), today with its partner Pfizer Inc. (NYSE: PFE), announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for vepdegestrant for the treatment of patients with estrogen receptor-positive (ER+)/human epidermal growth factor receptor 2-negative (HER2-), ESR1-mutated advanced or metastatic breast cancer who have previously received endocrine-based therapy. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date of June 5, 2026.

"Patients often face limited treatment options after first-line treatment and vepdegestrant demonstrated improved progression-free survival in patients with ESR1-mutated ER+/HER2- advanced breast cancer," said John Houston, Ph.D., Chairperson, Chief Executive Officer, and President at Arvinas. "With the efficacy and favorable tolerability seen in VERITAC-2, we believe vepdegestrant, if approved, has potential to be a best-in-class treatment option for patients in the second-line ESR1-mutant setting. We look forward to working alongside Pfizer and with the FDA to pursue vepdegestrant's approval and to ensure this important treatment option is made available to patients as rapidly as possible."

Vepdegestrant, an investigational oral PROTAC ER degrader, is being jointly developed by Arvinas and Pfizer. The NDA submission was based on data from VERITAC-2 (NCT05654623), a global, randomized Phase 3 clinical trial evaluating vepdegestrant versus fulvestrant. These data were [recently presented](#) at the American Society of Clinical Oncology (ASCO) 2025 Annual Meeting and were simultaneously published in [The New England Journal of Medicine](#).

About Vepdegestrant

Vepdegestrant is an investigational, orally bioavailable PROteolysis TArgeting Chimera (PROTAC) estrogen receptor degrader. 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 accepted the New Drug Application (NDA) for vepdegestrant for its use as a monotherapy in the treatment of adults with estrogen receptor-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-), ESR1-mutated advanced or metastatic breast cancer previously treated with endocrine-based therapy. Vepdegestrant has also been granted Fast Track designation by the FDA, underscoring the significant unmet need in this patient population and the potential for vepdegestrant to offer a meaningful new treatment option.

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 previously treated with a CDK4/6 inhibitor plus endocrine therapy. The trial enrolled 624 patients, 270 of whom had ESR1m positive disease, at 213 sites in 25 countries.

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 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; ARV-102, targeting LRRK2 for neurodegenerative disorders; and ARV-806, targeting KRAS G12D for mutated cancers, including pancreatic and colorectal cancers. 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: vepdegestrant's potential to be a best-in-class treatment option for patients with ER+/HER2- advanced or metastatic breast cancer with ESR1 mutations in the second line-plus setting; and vepdegestrant's potential approval and ensuring this treatment option is made available to patients as rapidly as possible. 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 approval timelines, including with respect to the New Drug Application for vepdegestrant; 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