Arvinas Announces FDA Approval of VEPPANU (vepdegestrant) for the Treatment of ESR1m, ER+/HER2- Advanced Breast Cancer

May 1, 2026

– VEPPANU ™ is the first-and-only FDA-approved PROTAC, a type of heterobifunctional protein degrader –

– Approval received in advance of FDA-assigned PDUFA date of June 5, 2026; Arvinas and Pfizer remain on track to announce selection of a third party –

– VEPPANU offers a new therapeutic option in ER+/HER2-, ESR1-mutated advanced or metastatic breast cancer, where treatment resistance remains a major clinical challenge –

NEW HAVEN, Conn., May 01, 2026 (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 granted approval for VEPPANU (vepdegestrant) for the treatment of adults with estrogen receptor-positive (ER+)/human epidermal growth factor receptor 2-negative (HER2-), estrogen receptor 1 (ESR1)-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy. This approval marks the first time the FDA has approved a PROteolysis TArgeting Chimera (PROTAC), a type of heterobifunctional protein degrader therapy.

“Today’s FDA approval is a transformative moment for Arvinas as we achieve our first approved medicine and the first-ever approved PROTAC therapy based on the technology we’ve pioneered since 2013,” said Randy Teel, Ph.D., President and Chief Executive Officer at Arvinas. “This milestone demonstrates that targeted protein degradation can translate into meaningful clinical impact. It also strengthens our confidence in the breadth and versatility of our exciting clinical pipeline across oncology, neurodegenerative, and neuromuscular diseases. We are especially encouraged by receiving FDA approval ahead of the June 5 PDUFA date and together with Pfizer, we are on track to announce selection of a third party to bring this new treatment option to patients as soon as possible.”

“For patients living with ESR1 mutant, ER+/HER2 advanced breast cancer, there have been minimal second-line treatment options once standard therapies are no longer effective,” said Erika Hamilton, M.D., Chief Development Officer, Late Phase, and Director, Breast Cancer Research, Sarah Cannon Research Institute, as well as a principal investigator of the VERITAC-2 trial. “The introduction of a new, targeted treatment is an encouraging development for this community and highlights meaningful innovation in the way this disease is treated. The approval of vepdegestrant gives clinicians another tool in the breast cancer treatment arsenal and brings renewed hope to individuals who need additional options.”

Breast cancer is the most common cancer among women worldwide, with many tumors driven by estrogen receptor signaling. While endocrine therapy remains a cornerstone of metastatic ER+/HER2- breast cancer treatment, up to 40-50% of patients treated with endocrine therapy and a CDK4/6 inhibitor have ESR1 mutations, resulting in endocrine resistance and poor prognosis. These patients often experience rapid disease progression and face limited options after first-line therapy. The FDA approval of VEPPANU addresses a significant unmet need, offering a new treatment option for adults with ESR1-mutant, ER+/HER2- advanced breast cancer by targeting a key biological driver of resistance to current therapies.

“The approval of VEPPANU is an important milestone for patients, their caregivers, and physicians,” said Noah Berkowitz, M.D., Ph.D., Chief Medical Officer at Arvinas. “VEPPANU addresses an unmet need for patients with this aggressive form of breast cancer who have progressed on their initial therapy. Today’s approval provides a new oral treatment option that showed improved progression free survival when compared to the current standard of care, fulvestrant, which is administered via an intramuscular injection.”

VEPPANU was discovered by Arvinas and jointly developed by Arvinas and Pfizer. FDA approval was granted based on data from VERITAC-2 (NCT05654623), a global, randomized, open-label, pivotal Phase 3 clinical trial evaluating vepdegestrant versus fulvestrant. In the trial, among patients with an ESR1 mutation (n=270), vepdegestrant demonstrated a statistically significant and clinically meaningful improvement in progression-free survival (PFS), reducing the risk of disease progression or death by 43% compared to fulvestrant. Median PFS was 5 months (95% CI: 3.7, 7.4) in the vepdegestrant arm and 2.1 months (95% CI: 1.9, 3.5) in the fulvestrant arm (hazard ratio 0.57 [95% CI: 0.42, 0.77]; p-value 0.0001). Overall survival was immature with 16% of deaths in this population at the time of the PFS analysis. The majority of adverse events (AEs) with vepdegestrant were low grade (Grade 1-2) and the most common (≥10%) adverse reactions, including laboratory abnormalities, were decreased white blood cells, increased AST, musculoskeletal pain, fatigue, decreased hemoglobin, decreased neutrophils, increased ALT, increased alkaline phosphatase, nausea, decreased blood potassium, increased bilirubin, decreased appetite, electrocardiogram QT prolonged, decreased platelets, and constipation.

Arvinas and Pfizer intend to jointly identify and select a third-party partner with the capabilities and expertise to maximize the commercial potential of VEPPANU. The companies are on track to announce selection of a third party.

Arvinas was originally founded based on pioneering research at Yale University, where Professor Craig Crews, Ph.D., co-authored the first-ever paper on PROTAC protein degraders.

Please see below for the Important Safety Information for VEPPANU. Please see full U.S. Prescribing Information for VEPPANU here.

What is VEPPANU?
VEPPANU is a prescription medicine to treat people with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *ESR1*-mutated advanced breast cancer or breast cancer that has spread to other parts of the body (metastatic), **and** whose disease has progressed after at least one line of endocrine-based therapy.

Your healthcare provider will perform a test to make sure that VEPPANU is right for you.

IMPORTANT SAFETY INFORMATION

What should I tell my healthcare provider before taking VEPPANU?

- **All your medical conditions, including if you:**
- have heart failure or heart rhythm problems, including QTc prolongation, and long QTc syndrome
- have low blood levels of potassium or magnesium
- are pregnant or plan to become pregnant. VEPPANU can harm your unborn baby.

  Females who are able to become pregnant:

  - Your healthcare provider may do a pregnancy test before you start treatment with VEPPANU.
  - Use effective birth control (contraception) during treatment with VEPPANU and for 2 weeks after the last dose.

  Males with female partners who are able to become pregnant:

  - Use effective birth control (contraception) during treatment with VEPPANU and for 2 weeks after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if VEPPANU passes into your breast milk. Do not breastfeed during treatment with VEPPANU and for 2 weeks after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the counter medicines, vitamins, and herbal supplements. VEPPANU and other medicines may affect the way each other works and may cause serious side effects.

What should I avoid while taking VEPPANU?
Avoid taking St. John's wort, eating grapefruit, or drinking grapefruit juice during with treatment with VEPPANU.

What are the possible side effects of VEPPANU?
VEPPANU can cause serious side effects, including:

- **Heart rhythm problems (QTc interval prolongation).** VEPPANU can cause changes in the electrical activity of your heart and may increase your risk of abnormal heart rhythm problems, and sudden death. Your healthcare provider will check your heart with a test called an electrocardiogram (ECG) and check your blood potassium and magnesium levels before and as needed during treatment with VEPPANU. Get emergency medical help right away if you get any signs and symptoms of abnormal heart rhythm, including:

  - feeling lightheaded or faint
  - dizziness
  - feeling that your heart is pounding or beating fast (heart palpitations)
  - shortness of breath
  - chest pain

The most common side effects of VEPPANU include:

- decreased white blood cell counts
- increased liver function tests
- muscle and bone pain
- tiredness
- decreased red blood cell counts
- nausea
- decreased potassium levels in your blood
- decreased appetite
- abnormal electrocardiogram (QT prolonged)
- decreased platelet counts
- constipation

Your healthcare provider may decrease your dose, temporarily stop, or completely stop treatment with VEPPANU, if you develop

certain side effects.

VEPPANU may affect fertility in males and in females who are able to become pregnant. Talk to your healthcare provider if this is a concern for you. These are not all of the possible side effects of VEPPANU.

Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

About the VERITAC-2 Clinical Trial
The Phase 3 VERITAC-2 clinical trial (NCT05654623) is a global, randomized, open-label 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.

About VEPPANU
VEPPANU (vepdegestrant) is an orally bioavailable PROteolysis TArgeting Chimera (PROTAC), estrogen receptor degrader approved in the U.S. for 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, as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy.

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. In September 2025, Arvinas and Pfizer announced their plan to jointly select a third party for the commercialization and potential further development of vepdegestrant.

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, Arvinas 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, with its partner Pfizer, developed the first-and-only U.S. Food and Drug Administration (FDA) approved PROTAC, a type of heterobifunctional protein degrader, VEPPANU (vepdegestrant), for the treatment of adults with estrogen receptor-positive (ER+)/human epidermal growth factor receptor 2-negative (HER2-), ESR1-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy.

Arvinas is currently progressing multiple investigational drugs through clinical development programs, including ARV-102, targeting LRRK2 for neurodegenerative disorders; ARV-806, targeting KRAS G12D for mutated cancers, including pancreatic, colorectal, and non-small cell lung cancers; ARV-393, targeting BCL6 for relapsed/refractory non-Hodgkin Lymphoma; and ARV-027, targeting the polyglutamine-expanded androgen receptor, or polyQ-AR, in skeletal muscle. 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: Arvinas' belief in the potential of PROTAC degraders; Arvinas' plans, with Pfizer, to jointly identify and select a third party partner with the capabilities and expertise to maximize the commercial potential of VEPPANU™ (vepdegestrant); Arvinas' belief that it is, with Pfizer, on track to announce selection of a partner capable of bringing VEPPANU to patients, and the timing of any such announced partner brining the treatment option to patients; and Arvinas' belief in the breadth and versatility of its clinical pipeline across oncology, neurodegenerative, and neuromuscular diseases. 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; risks and uncertainties related to the identification of a third party for the commercialization and potential future development of VEPPANU; whether VEPPANU will be commercially available when

expected; the potential demand and market potential and acceptance of, VEPPANU, including estimates regarding the potential market opportunity; the competitive landscape for VEPPANU; risks related to Arvinas' expectations regarding the potential clinical benefit of VEPPANU to patients; the risk that any regulatory approval may be subject to significant limitations on use or subject to withdrawal or other adverse actions by the applicable regulatory authority; the uncertainties inherent in research and development, including clinical trial results; regulatory actions or delays or government regulation generally; 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, 2025 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:
Alyssa Kuciunas
+1 (331) 481-3751
Alyssa.kuciunas-c@arvinas.com