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Arvinas and Pfizer Announce Positive Topline Results from Phase 3 VERITAC-2 Clinical Trial

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– VERITAC-2 achieved its primary endpoint in the estrogen receptor 1-mutant population, demonstrating statistically significant and clinically meaningful improvement in progression-free survival –

– Vepdegestrant is the first PROTAC degrader to demonstrate clinical benefit in a Phase 3 trial –

NEW HAVEN, Conn. and NEW YORK, March 11, 2025 – Arvinas, Inc. (Nasdaq: ARVN) and Pfizer Inc. (NYSE: PFE) today announced positive topline results from the Phase 3 VERITAC-2 clinical trial (NCT05654623) evaluating vepdegestrant monotherapy versus fulvestrant in adults with estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) advanced or metastatic breast cancer whose disease progressed following prior treatment with cyclin-dependent kinase (CDK) 4/6 inhibitors and endocrine therapy. These are the first pivotal data for vepdegestrant, a potential first-in-class investigational oral PROteolysis TArgeting Chimera (PROTAC) ER degrader.

The trial met its primary endpoint in the estrogen receptor 1-mutant (ESR1m) population, demonstrating a statistically significant and clinically meaningful improvement in progression-free survival (PFS) compared to fulvestrant. The results exceeded the pre-specified target hazard ratio of 0.60 in the ESR1m population. The trial did not reach statistical significance in improvement in PFS in the intent-to-treat (ITT) population.

“The first Phase 3 data readout for a PROTAC degrader represents a significant achievement and these data show that vepdegestrant has the potential to provide clinically meaningful outcomes for thousands of patients with metastatic breast cancer whose tumors harbor estrogen receptor 1 mutations,” said John Houston, Ph.D., Chairperson, Chief Executive Officer and President at Arvinas. “We want to thank the patients and investigators who participated in this trial, and we look forward to sharing these data with health authorities as well as at a medical conference in 2025.”

Overall survival was not mature at the time of the analysis, with less than a quarter of the required number of events having occurred. The trial will continue to assess overall survival as a key secondary endpoint. In the trial, vepdegestrant was generally well tolerated and its safety profile was consistent with what has been observed in previous studies. Detailed results from VERITAC-2 will be submitted for presentation at a medical meeting later this year, and these data will be shared with global regulatory authorities to potentially support regulatory filings.

“Patients with advanced ER+/HER2- metastatic breast cancer face significant clinical challenges, with limited treatment options following disease progression and the development of resistance to available endocrine therapies,” said Megan O’Meara, M.D., Interim Chief Development Officer, Pfizer Oncology. “These data from VERITAC-2 support the potential of vepdegestrant to give patients whose tumors harbor ESR1 mutations

additional time without disease progression, compared to fulvestrant."

Vepdegestrant is an investigational oral PROTAC ER degrader for ER+/HER2- breast cancer being jointly developed by Arvinas and Pfizer and is designed to harness the body's natural protein disposal system to specifically target and degrade the ER. In February 2024, the companies announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for the investigation of vepdegestrant for monotherapy in the treatment of adults with ER+/HER2- advanced or metastatic breast cancer previously treated with endocrine-based therapy.

About Metastatic Breast Cancer
About 2.3 million new breast cancer diagnoses were reported globally in 2022,[1] and it is estimated there will be nearly 320,000 people diagnosed with breast cancer in the U.S. in 2025.[2] Estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) breast cancer accounts for approximately 70% of all cases.[3]

Nearly 30% of women initially diagnosed with early-stage breast cancer will ultimately develop metastatic breast cancer (MBC),[4] the most advanced stage in which the disease has spread beyond the breast to other parts of the body. Treatment advances have helped those with MBC better manage symptoms, slow tumor growth, and may allow them to live longer, but most patients ultimately develop resistance to current standard-of-care treatments in the first-line setting and experience disease progression. ESR1 mutations are a common cause of acquired resistance and are found in approximately 40% of patients in the second-line setting.[5 6 7]

About the VERITAC-2 Clinical Trial
The Phase 3 VERITAC-2 clinical trial (NCT05654623) is a global randomized study 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 26 countries who had previously received treatment with a CDK4/6 inhibitor plus endocrine therapy.

Patients were randomized 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. The primary endpoint was progression-free survival (PFS) in the intent-to-treat and ESR1m populations as determined by blinded independent central review. Overall survival is a 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) for the treatment of patients with ER-positive (ER+)/human epidermal growth factor receptor 2 (HER2)-negative (ER+/HER2-) breast cancer. Vepdegestrant is being developed as a potential monotherapy and as part of combination therapy across multiple treatment settings for ER+/HER2- metastatic breast cancer.

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.

About Pfizer Oncology
At Pfizer Oncology, we are at the forefront of a new era in cancer care. Our industry-leading portfolio and extensive pipeline includes three core mechanisms of action to attack cancer from multiple angles, including small molecules, antibody-drug conjugates (ADCs), and bispecific antibodies, including other immune-oncology biologics. We are focused on delivering transformative therapies in some of the world's most common cancers, including breast cancer, genitourinary cancer, hematology-oncology, and thoracic cancers, which includes lung cancer. Driven by science, we are committed to accelerating breakthroughs to help people with cancer live better and longer lives.

About Pfizer: Breakthroughs That Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For 175 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on X at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Arvinas 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 having the potential to provide clinically meaningful outcomes for thousands of patients with metastatic breast cancer whose tumors harbor estrogen receptor 1 mutations; Arvinas' and Pfizer's plans to share data from the Phase 3 VERITAC-2 clinical trial with health authorities, including to potentially support regulatory filings, as well as at a medical conference in 2025; and vepdegestrant's development as a potential monotherapy and as part of combination therapy across multiple treatment settings for estrogen receptor positive, human epidermal growth factor receptor 2 negative metastatic breast cancer. 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 and as part of combination therapy; whether Arvinas will be able to successfully conduct and complete development for its other product candidates, including ARV-393 and ARV-102; 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.

Pfizer Disclosure Notice:
The information contained in this release is as of March 11, 2025. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer Oncology and vepdegestrant, including its potential benefits, vepdegestrant's potential for adults with ER+/HER2- advanced or metastatic breast cancer whose disease progressed following prior treatment with CDK 4/6 inhibitors and endocrine-based therapy and plans to share these data with global regulatory authorities to potentially support regulatory filings, that involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements.

Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; whether the VERITAC-2 trial will meet the secondary endpoint for overall survival; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for any potential indication for vepdegestrant; whether and when any such applications that may be filed for vepdegestrant may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy, and, if approved, whether vepdegestrant will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of vepdegestrant; whether the collaboration between Pfizer and Arvinas will be successful; uncertainties regarding the impact of COVID-19 on our business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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[1] World Health Organization. (2024, March 13). *Breast cancer.* World Health Organization. https://www.who.int/news-room/fact-sheets/detail/breast-cancer
[2] Siegel RL, Kratzer TB, Giaquinto AN, Sung H, Jemal A. Cancer statistics, 2025. CA Cancer J Clin. 2025 Jan-Feb;75(1):10-45. doi: 10.3322/caac.21871. Epub 2025 Jan 16. PMID: 39817679; PMCID: PMC11745215.
[3] Surveillance, Epidemiology, and End Results Program Data, https://seer.cancer.gov/statfacts/html/breast-subtypes.html.
[4] Redig AJ, McAllister SS. Breast cancer as a systemic disease: a view of metastasis.?*J Intern Med.* 2013;274(2):113-126. doi:10.1111/joim.12084.
[5] Bidard F-C, et al. Elacestrant (oral selective estrogen receptor degrader) Versus Standard Endocrine Therapy for Estrogen Receptor–Positive, Human Epidermal Growth Factor Receptor 2–Negative Advanced Breast Cancer: Results From the Randomized Phase III EMERALD Trial. Journal of Clinical Onoclogy. 2022 May https://doi.org/10.1200/JCO.22.00338.
[6] Kalinsky, K. Abemaciclib Plus Fulvestrant in Advanced Breast Cancer After Progression on CDK4/6 Inhibition: Results From the Phase III postMONARCH Trial. Journal of Clinical Oncology. 2024 Dec. https://doi.org/10.1200/JCO-24-0208.
[7] Tolaney, S. et al. AMEERA-3: Randomized Phase II Study of Amcenestrant (Oral Selective Estrogen Receptor Degrader) Versus Standard Endocrine Monotherapy in Estrogen Receptor–Positive, Human Epidermal Growth Factor Receptor 2–Negative Advanced Breast Cancer. Journal of Clinical Oncology. https://ascopubs.org/doi/full/10.1200/JCO.22.02746.

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