Arvinas and Pfizer’s Vepdegestrant (ARV-471) Receives FDA Fast Track Designation for the Treatment of Patients with ER+/HER2- Metastatic Breast Cancer

February 6, 2024

-- Vepdegestrant is an investigational PROteolysis Targeting Chimera (PROTAC®) protein degrader designed to target and degrade the estrogen receptor (ER) protein --

NEW HAVEN, Conn. and NEW YORK, Feb. 06, 2024 (GLOBE NEWSWIRE) -- Arvinas, Inc. (Nasdaq: ARVN) and Pfizer Inc. (NYSE: PFE) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the investigation of vepdegestrant (ARV-471) for monotherapy in the treatment of adults with estrogen receptor (ER) positive/human growth epidermal growth factor 2 (HER2) negative (ER+/HER2-) locally advanced or metastatic breast cancer previously treated with endocrine-based therapy. Vepdegestrant is a novel oral PROteolysis Targeting Chimera (PROTAC®) ER degrader that is being jointly developed by Arvinas and Pfizer.

As described by the FDA, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to patients earlier. Vepdegestrant as a monotherapy is being studied in the ongoing Phase 3 VERITAC-2 clinical trial, which is evaluating vepdegestrant or fulvestrant in patients with locally advanced or metastatic ER+/HER2- breast cancer who have been previously treated with an endocrine-based therapy.

"We are focused on the persisting unmet needs of people with ER+/HER2- breast cancer and doing all that we can to expedite the development of vepdegestrant as a novel, oral ER-targeted potential therapy for this patient community,” said John Houston, Ph.D., Arvinas Chairperson, Chief Executive Officer, and President. “We are pleased the FDA has granted Fast Track designation for vepdegestrant, and we continue to believe this investigational drug has the potential to harness the body’s own natural protein disposal system to selectively and efficiently degrade and remove disease-causing proteins."

“The receipt of Fast Track designation reinforces the potential of vepdegestrant to provide an important new therapeutic option for people with ER+/HER2- breast cancer whose disease has progressed,” said Roger Dansey, M.D., Chief Development Officer, Oncology, Pfizer. “We are proud to continue our legacy of developing innovative treatment options for people impacted by metastatic breast cancer and look forward to working with the FDA as we advance our development program for vepdegestrant.”

About Vepdegestrant (ARV-471) and its Clinical Trials
Vepdegestrant is an investigational, orally bioavailable PROTAC 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.

In preclinical studies, vepdegestrant demonstrated up to 97% ER degradation in tumor cells, induced robust tumor shrinkage when dosed as a single agent in multiple ER-driven xenograft models, and showed increased anti-tumor activity when compared to a standard of care agent, fulvestrant, both as a single agent and in combination with a CDK4/6 inhibitor. In July 2021, Arvinas announced a global collaboration with Pfizer for the co-development and co-commercialization of vepdegestrant; Arvinas and Pfizer will equally share worldwide development costs, commercialization expenses, and profits. Ongoing and planned clinical trials will continue to monitor and evaluate the safety and anti-tumor activity of vepdegestrant.

Vepdegestrant is currently being evaluated as a monotherapy in the second-line setting in the ongoing Phase 3 VERITAC-2 clinical trial and in the first-line setting in combination with palbociclib in the ongoing study lead-in cohort of the Phase 3 VERITAC-3 clinical trial. Vepdegestrant is also being evaluated for potential combination therapy with abemaciclib, ribociclib, samuraciclib, everolimus, and with Pfizer’s investigational novel CDK4 inhibitor, PF-07220060.

About Arvinas
Arvinas is a clinical-stage biotechnology company dedicated to improving the lives of patients suffering from debilitating and life-threatening diseases through the discovery, development, and commercialization of therapies that degrade disease-causing proteins. Arvinas uses its proprietary PROTAC Discovery Engine platform to engineer proteolysis targeting chimeras, or PROTAC targeted protein degraders, that are designed to harness the body’s own natural protein disposal system to selectively and efficiently degrade and remove disease-causing proteins. In addition to its robust preclinical pipeline of PROTAC protein degraders against validated and “undruggable” targets, the company has three investigational clinical-stage programs: ARV-766 and bavdegalutamide for the treatment of men with metastatic castration-resistant prostate cancer; and vepdegestrant (ARV-471) for the treatment of patients with locally advanced or metastatic ER+/HER2- breast cancer. For more information, visit www.arvinas.com.

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 the potential advantages and therapeutic benefits of vepdegestrant (ARV-471), and the ability to realize the benefits from vepdegestrant receiving Fast Track designation. All statements, other than statements of historical facts, contained in this press release are forward-looking statements. The words “believe,” “expect,” “may,” “plan,” “potential,” “will,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make as a result of various risks and uncertainties, including but not limited to: Fast Track designation may not result in a more expedited development or regulatory review process, and such a designation does not increase the likelihood that vepdegestrant will receive marketing approval; Fast Track designation does not change the standards for regulatory approval; the FDA may later decide that vepdegestrant no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened; our and Pfizer Inc’s (“Pfizer”) performance of our respective obligations with respect to our collaboration with Pfizer; whether we and Pfizer will be able to successfully

conduct and complete clinical development for vepdegestrant and obtain marketing approval for and commercialize vepdegestrant on our current timelines or at all; whether our cash and cash equivalent resources will be sufficient to fund our foreseeable and unforeseeable operating expenses and capital expenditure requirements; and other important factors discussed in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2022, and subsequent other reports on file with the Securities and Exchange Commission. The forward-looking statements contained in this press release reflect our current views with respect to future events, and we assume 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 our views as of any date after the date of this release.

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 game-changing mechanisms of action to attack cancer from multiple angles, including antibody-drug conjugates (ADCs), small molecules, bispecifics and other immunotherapies. We are focused on delivering transformative therapies in some of the world’s most common cancers, including breast cancer, genitourinary cancer and hematologic malignancies, as well as melanoma, gastrointestinal, gynecological and thoracic cancers, which includes lung cancer. Driven by science, we are committed to accelerating breakthroughs to extend and improve patients’ lives.

Pfizer Disclosure Notice
The information contained in this release is as of February 6, 2024. 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 and Arvinas’ investigation of vepdegestrant (ARV-471) for monotherapy in the treatment of adults with estrogen receptor (ER) positive/human growth epidermal growth factor 2 (HER2) negative (ER+/HER2-) locally advanced or metastatic breast cancer previously treated with endocrine-based therapy, including its potential benefits and its Phase 3 development program, that involves 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; 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 vepdegestrant; whether and when any such applications 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; the impact of COVID-19 on Pfizer’s 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, 2022 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.

Arvinas Contacts

Investor Contact:
Jeff Boyle, Arvinas Investor Relations
347-247-5089
Jeff.Boyle@arvinas.com

Media Contact:
Kathleen Murphy, Arvinas Communications
760-622-3771
Kathleen.Murphy@arvinas.com

Pfizer Contacts

Investor Contact:
+1 (212) 733-4848
IR@pfizer.com

Media Contact:
+1 (212) 733-1226
PfizerMediaRelations@pfizer.com