Pfizer Logo

Arvinas and Pfizer Awarded Innovation Passport Designation by the U.K. Innovative Licensing and Access Pathway Steering Group for Vepdegestrant, an Investigational PROTAC® ER degrader being developed in ER+/HER2- Breast Cancer

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-- Designation indicates entry into the U.K.'s Innovative Licensing and Access Pathway (ILAP) –

NEW HAVEN, Conn. and NEW YORK, July 31, 2023 – Arvinas, Inc. (Nasdaq: ARVN) and Pfizer Inc. (NYSE: PFE) today announced that the U.K. Innovative Licensing and Access Pathway Steering Group, which consists of The All Wales Therapeutics and Toxicology Centre (AWTTC), The Medicines and Healthcare products Regulatory Agency (MHRA), the National Institute for Health and Care Excellence (NICE), and the Scottish Medicines Consortium (SMC), has awarded an Innovation Passport to vepdegestrant (ARV-471), an investigational PROTAC® ER degrader, for the treatment of patients with estrogen receptor (ER)+/ human epidermal growth factor receptor (HER)2- locally-advanced breast cancer or metastatic breast cancer.

The Innovation Passport is the entry point for the Innovative Licensing and Access Pathway (ILAP). The goal of ILAP is to accelerate the time to market facilitating patient access to medicines in the U.K. The Innovation Passport application is the first step in the ILAP process, which activates the Medicines and Healthcare products Regulatory Agency (MHRA) and its partner agencies, including the National Institute for Health and Care Excellence (NICE), and the Scottish Medicines Consortium (SMC) and to develop a roadmap for regulatory and development milestones.

"This esteemed acknowledgment underscores our commitment to advancing medicine and delivering transformative solutions for patients," said John Houston, Ph.D., president and chief executive officer at Arvinas. "Arvinas is hopeful our investigational PROTAC® ER degrader, vepdegestrant, will have the potential to be an endocrine therapy backbone for ER+/HER2-breast cancer."

"The Innovation Passport designation opens the door for Pfizer and Arvinas to discuss access considerations for potential future indications for vepdegestrant," said Chris Boshoff, M.D., Ph.D., chief oncology research and development officer and executive vice president at Pfizer. "We look forward to an ongoing dialogue with regulators, health technology assessment agencies and other partners, supporting a timely review as we aim to bring this potential medicine to patients as quickly as possible."

Multiple Phase 1, 2, and 3 studies with vepdegestrant are enrolling globally, including the VERITAC-2 Phase 3 2L/3L clinical trial of vepdegestrant as a monotherapy for the treatment of patients with ER+/HER2- metastatic breast cancer, which is anticipated to complete enrollment in 2024. Arvinas and Pfizer recently initiated the study lead-in of the VERITAC-3 Phase 3 trial of vepdegestrant and palbociclib as a first-line treatment in patients with ER+/HER2- locally advanced or metastatic breast cancer. The study lead-in will identify the dose of palbociclib for the randomized portion of the study. The companies also plan to submit additional data from the Phase 1b combination trial with palbociclib at a medical congress during the second half of 2023.

About ILAP
The U.K. Medicines and Healthcare products Regulatory Agency (MHRA) launched ILAP at the start of 2021 in order to accelerate the development and access to promising medicines in the early stages of development. The pathway, part of the UK's plan to attract life sciences development in the post-Brexit era, features enhanced input and interactions with MHRA and other stakeholders. Other benefits of ILAP include access to a range of development tools, such as the potential for a 150-day accelerated Marketing Authorization Application (MAA) assessment, rolling review and a continuous benefit risk assessment. More information about ILAP can be found here.

About vepdegestrant (ARV-471)
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 early and locally advanced or metastatic ER positive/human epidermal growth factor receptor 2 (HER2) negative (ER+/HER2-) breast cancer. Use of vepdegestrant in the ongoing and planned clinical trials will continue to monitor and evaluate patient safety and anti-tumor activity.

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.

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 preclinical pipeline of PROTAC protein degraders against validated and "undruggable" targets, the company has three investigational clinical-stage programs: bavdegalutamide and ARV-766 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 bavdegalutamide (ARV-110), vepdegestrant (ARV-471), and ARV-766 and our other discovery programs, the development and regulatory status of our product candidates, such as statements with respect to the potential of our lead product candidates bavdegalutamide, vepdegestrant, ARV-

766 and other candidates in our pipeline, and, including the initiation of and timing of the timing of clinical trials, including the timing to complete enrollment, as well as the presentation and/or publication of data from those trials and plans for registration for our product candidates, and our discovery programs that may lead to our development of additional product candidates, the potential utility of our technology, our plans with respect to submission of investigational new drug/clinical trial authorization applications, the potential commercialization of any of our product candidates, and the sufficiency of our cash resources. All statements, other than statements of historical facts, contained in this press release, including statements regarding our 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,” “might,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “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: 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; whether we will be able to successfully conduct and complete development for bavdegalutamide, ARV-766 and our other product candidates, including whether we initiate and complete clinical trials for our product candidates and receive results from our clinical trials on our expected timelines or at all; obtain marketing approval for and commercialize vepdegestrant, bavdegalutamide, ARV-766 and our other product candidates 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 of Form 10-K for the year ended December 31, 2021 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 subsequent to the date of this release.

About Pfizer Oncology
At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference in the lives of people living with cancer. Today, we have an industry-leading portfolio of 24 approved innovative cancer medicines and biosimilars across more than 30 indications, including breast, genitourinary, colorectal, blood and lung cancers, as well as melanoma.

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 more than 170 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 Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on

Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice:
The information contained in this release is as of July 31, 2023. 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 vepdegestrant (ARV-471) and a global collaboration between Pfizer and Arvinas to develop and commercialize ARV-471, including their potential benefits, 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 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 the clinical studies; whether and when any applications may be filed for ARV-471 for any potential indications in any jurisdictions; whether and when regulatory authorities may approve any potential applications that may be filed for ARV-471 in any jurisdictions, 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 ARV-471 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 ARV-471; whether the collaboration between Pfizer and Arvinas will be successful; uncertainties regarding 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.

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