



Arvinas Updates Guidance for First- and Second-Line Phase 3 Combination Trials with Vepdegestrant, Highlights Upcoming Milestones, and Provides Corporate Update

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– Vepdegestrant to be combined with Pfizer’s novel investigational CDK4 inhibitor atirmociclib in a first-line Phase 3 trial planned to initiate in 2025; a second-line Phase 3 combination trial will combine vepdegestrant with a CDK4/6 inhibitor, also planned to initiate in 2025 –

– Topline data from the monotherapy Phase 3 VERITAC-2 trial of vepdegestrant anticipated in 1Q25 –

– The Company recently initiated a Phase 1 trial with PROTAC LRRK2 degrader ARV-102 in patients with Parkinson’s disease –

– Data disclosures anticipated from multiple clinical and pre-clinical programs, including ARV-102 and ARV-393, and planned IND submission for a PROTAC KRAS G12D degrader in 2025 –

NEW HAVEN, Conn., Jan. 10, 2025 (GLOBE NEWSWIRE) -- Arvinas, Inc. (Nasdaq: ARVN), a clinical-stage biotechnology company creating a new class of drugs based on targeted protein degradation, today announced updated guidance for the planned first- and second-line combination clinical trials for vepdegestrant in patients with locally advanced or metastatic estrogen receptor positive (ER+)/human epidermal growth factor receptor 2 negative (HER2-) breast cancer, highlighted key upcoming milestones and provided a corporate update.

“We are on the cusp of a major transformation in 2025, with the potential to provide significant benefit to patients and meaningful value to our stockholders,” said John Houston, Ph.D., Chairperson, Chief Executive Officer and President at Arvinas. “We are on track to report topline results from our first Phase 3 trial in the first quarter and to initiate two additional Phase 3 trials by the end of the year. In the first half of 2025, we plan to present the first-in-human data from ARV-102, our PROTAC LRRK2 degrader, which we believe will highlight the potential value that our PROTAC degraders may offer for patients with neurodegenerative diseases. And finally, we plan to share initial data from our Phase 1 trial with ARV-393, our PROTAC BCL6 degrader, which will provide an early look the tolerability and efficacy in patients with B-cell lymphomas.”

Select milestones anticipated in 2025

Vepdegestrant: Oral PROTAC ER degrader

As part of Arvinas’ global collaboration with Pfizer, in 2025 the companies plan to:

- Announce topline data for the VERITAC-2 Phase 3 monotherapy clinical trial in patients with second-line-plus ER+/HER2- metastatic breast cancer (mBC) (1Q25).
- Initiate two new Phase 3 combination trials in patients with ER+/HER2- mBC (pending emerging data and regulatory feedback):
 - First-line Phase 3 combination trial with Pfizer’s novel investigational CDK4 inhibitor, atirmociclib.
 - Second-line Phase 3 combination trial with a CDK4/6 inhibitor.

With the prioritization of the vepdegestrant plus atirmociclib combination for the first-line setting, the VERITAC-3 trial evaluating vepdegestrant plus palbociclib in the first-line will not proceed beyond the study lead-in.

ARV-102: Oral PROTAC LRRK2 degrader

- Present single-ascending dose data from the ongoing Phase 1 clinical trial in healthy volunteers in an oral session at the Alzheimer’s Disease/Parkinson’s Disease (AD/PD) conference in Vienna, Austria (April 1-4, 2025).
- Complete enrollment and present initial data from the ongoing Phase 1 clinical trial in patients with Parkinson’s disease.

ARV-393: Oral PROTAC BCL6 degrader

- Present initial data from the ongoing Phase 1 clinical trial in patients with B-cell lymphomas (NCT06393738).

Novel PROTAC KRAS G12D degrader

- File an Investigational New Drug (IND) application.

Corporate update

Alex Santini, Arvinas’ Senior Vice President, Global and U.S. Market Access, has been appointed interim Chief Commercial

Officer, effective January 17, 2025. Mr. Santini joined Arvinas in 2023 with more than 30 years of experience managing and leading commercial organizations. Previously, he was Executive Vice President, Chief Commercial Officer, at Lexicon Pharmaceuticals. Prior to Lexicon, Mr. Santini was Executive Vice President, U.S. Market Access at Bayer, where he served on the U.S. Executive Committee. Mr. Santini's prior experience also includes serving as Senior Vice President, Market Access at Nektar Therapeutics, and he began his career at Berlex Laboratories, where he served in roles of increasing responsibility in the commercial organization.

John Northcott, Chief Commercial Officer, is leaving the Company for personal reasons, effective January 17, 2025.

"Our commercial organization couldn't be in a better position, and I look forward to working closely with Alex," continued Dr. Houston. "He has been a highly valued member of the Arvinas team for multiple years, and his well-established ability to build and lead an outstanding commercial team will be invaluable as we prepare for our potential first launch alongside our partners at Pfizer. We thank John for his contributions to the business, particularly his efforts to begin building a strong commercial organization for launch."

About Vepdegestrant

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. 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- locally 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](#).

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 plans and expected timing of initiation of two Phase 3 vepdegestrant combination clinical trials, in the first- and second-line settings, pending emerging data and regulatory feedback; the expected timing to report topline data from the VERITAC-2 Phase 3 monotherapy clinical trial of vepdegestrant; the potential to provide significant benefit to patients and meaningful value to stockholders in 2025; the plans and timing of presentation of first-in-human data from ARV-102 and the company's belief that such data will highlight the potential value that its PROTAC degraders may offer patients with neurodegenerative diseases; the plans and timing of sharing initial data from the company's Phase 1 clinical trial of ARV-393; and the plans and expected timing of filing an investigational new drug application for a PROTAC KRAS G12D degrader. 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," "might," "plan," "predict," "project," "target," "goal," "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.

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: Arvinas' and Pfizer's performance of the respective obligations with respect to Arvinas' collaboration with Pfizer; whether Arvinas and Pfizer will be able to successfully conduct and complete clinical development for vepdegestrant; whether Arvinas will be able to successfully conduct and complete development for its other product candidates, including whether Arvinas initiates and completes clinical trials for its product candidates and receives results from its clinical trials on its expected timelines or at all; Arvinas' ability to protect its intellectual property portfolio; 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, 2023 and subsequent other reports, including its quarterly 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.

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