Arvinas Receives Authorization to Proceed for ARV-471, a PROTAC® Protein Degrader to Treat Patients with Locally Advanced or Metastatic ER+ / HER2- Breast Cancer

June 25, 2019

- Initiation of Phase 1 Trial expected in the third quarter of 2019

- ARV-471 will be Arvinas' second targeted PROTAC ® protein degrader to enter the clinic

NEW HAVEN, Conn., June 25, 2019 (GLOBE NEWSWIRE) -- Arvinas, Inc. (Nasdaq: ARVN), a biotechnology company creating a new class of drugs based on targeted protein degradation, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug application (IND) for ARV-471, an oral estrogen receptor (ER) PROTAC® protein degrader, designed to selectively target ER for the treatment of patients with locally advanced or metastatic ER positive / HER2 negative breast cancer. Arvinas expects to initiate a Phase 1 clinical trial for ARV-471 in the third quarter of 2019.

"ARV-471 is our second program in six months to receive IND clearance, and we are pleased to be advancing it into the clinic and progressing Arvinas' portfolio of PROTAC® protein degraders for the treatment of patients with cancer and other life-threatening diseases," said John Houston, Ph.D., President and CEO of Arvinas. "We hope the activity ARV-471 demonstrated preclinically will translate into a new, beneficial treatment for patients with locally advanced or metastatic ER positive/HER2 negative breast cancer."

In the United States, breast cancer is the second most common cancer and the second leading cause of cancer death in women. The American Cancer Society estimates that in 2019, there will be approximately 268,000 women diagnosed with invasive breast cancer in the United States. Metastatic breast cancer accounts for approximately 6% of newly diagnosed cases. Approximately 80% of newly diagnosed breast cancers are ER positive, with many patients developing resistance to current treatment options over time.

ARV-471 is a PROTAC® protein degrader specifically designed to target and degrade ER. The Phase 1 trial will assess the safety, tolerability, and pharmacokinetics of ARV-471, and will also include measures of anti-tumor activity and pharmacodynamic readouts as secondary endpoints.

In preclinical studies, ARV-471 demonstrated near-complete ER degradation in tumor cells, induced robust tumor shrinkage when dosed as a single agent in multiple ER-driven xenograft models, and showed superior anti-tumor activity as a single agent and in combination with a CDK4/6 inhibitor when compared to a standard of care agent, fulvestrant, dosed as single agent or in combination with a CDK4/6 inhibitor. Arvinas believes the differentiated pharmacology of ARV-471, including its iterative degradation activity, has the potential to translate into meaningful clinical benefit for patients.

About Arvinas
Arvinas is a clinical-stage biopharmaceutical 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 technology 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. The company's lead program, ARV-110 for the treatment of patients with metastatic castrate-resistant prostate cancer, began a Phase 1 clinical trial in the first quarter of 2019. For more information, visit www.arvinas.com.

Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties, including statements regarding the development and regulatory status of our product candidates, including the timing of our clinical trial for ARV-471, and preliminary data from our clinical trial for ARV-471 and the potential advantages and therapeutic potential of our product candidates. All statements, other than statements of historical facts, contained in this press release, including statements regarding our strategy, future operations, 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: whether we will be able to successfully initiate and conduct a Phase 1 clinical trial for ARV-471, and complete our clinical trials for our product candidates on our expected timelines, or at all, whether our cash resources will be sufficient to fund our foreseeable and unforeseeable operating expenses and capital expenditure requirements on our expected timeline and other important factors discussed in the "Risk Factors" sections contained in our quarterly and annual 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.

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