



Arvinas Receives Authorization to Proceed for its IND Application for PROTAC™ Therapy to Treat Patients with Metastatic Castration-Resistant Prostate Cancer

January 4, 2019

Expects Enrollment of Phase 1 Trial to Begin in the First Quarter of 2019

NEW HAVEN, Conn., Jan. 04, 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-110, an oral androgen receptor (AR) PROTAC™ protein degrader, for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC). Arvinas expects to begin enrollment of a Phase 1 clinical trial for ARV-110 in the first quarter of this year.

"This IND clearance is a key step forward for Arvinas and for the field of protein degradation," said John Houston, Ph.D., President and CEO of Arvinas. "Our PROTAC platform has demonstrated exciting promise in preclinical studies and represents an entirely new approach to treating patients with mCRPC and many other diseases. We hope ARV-110 will deliver a much-needed new therapeutic option for patients, and we expect to dose our first patient in the first quarter of 2019."

ARV-110 was developed using Arvinas' proprietary technology platform – PROTAC (proteolysis-targeting chimera) protein degraders – that uses small molecules to harness the body's own natural protein recycling system (the ubiquitin proteasome system) to selectively and efficiently remove disease-causing proteins. ARV-110 is a PROTAC protein degrader specifically designed to target and degrade AR, and has demonstrated activity in preclinical models of AR overexpression and AR mutations, which are both common resistance mechanisms to current standard-of-care agents in men with prostate cancer. The Phase 1 study will investigate the safety and tolerability of ARV-110 in patients with mCRPC who have progressed on at least two standard of care treatment regimens and includes exploratory measures of efficacy.

About Arvinas

Arvinas is a biopharmaceutical company dedicated to improving the lives of patients suffering from debilitating and life-threatening diseases through the discovery, development, and commercialization of therapies to degrade disease-causing proteins. Arvinas uses its proprietary technology platform to engineer proteolysis targeting chimeras, or PROTAC™ protein degraders, that are designed to harness the body's own natural protein recycling system to selectively and efficiently degrade and remove disease-causing proteins. For more information, see 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-110. 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 a Phase 1 clinical trial for ARV-110, file an IND 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 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.

Contacts for Arvinas

Investors

Randy Teel, VP Corporate Development
ir@arvinas.com

Media

Cory Tromblee, ScientPR
pr@arvinas.com



Source: Arvinas Inc.