



Arvinas Announces Initiation of Patient Dosing in the First Phase 1 Clinical Trial of PROTAC™ Protein Degradar, ARV-110

March 25, 2019

Study to Evaluate Safety and Tolerability of Androgen Receptor (AR)-targeted PROTAC™ Protein Degradar in Patients with Metastatic Castration-Resistant Prostate Cancer

NEW HAVEN, Conn., March 25, 2019 (GLOBE NEWSWIRE) -- Arvinas, Inc. (Nasdaq: ARVN), a biopharmaceutical company creating a new class of therapies that degrade disease-causing proteins, today announced the initiation of patient dosing in its Phase 1 clinical trial of ARV-110, the company's oral androgen receptor (AR)-targeted PROTAC™ protein degrader. The study will evaluate the safety, tolerability, and pharmacokinetics of ARV-110 in patients with metastatic castration-resistant prostate cancer (mCRPC) who have progressed on standard of care therapies. Arvinas believes ARV-110 is the first in a new class of targeted protein degraders to enter human clinical trials and anticipates preliminary data from the study in the second half of 2019.

"With ARV-110 we are harnessing the body's natural protein disposal system to degrade AR, a key contributor to the progression of prostate cancer," said John Houston, Ph.D., President and CEO of Arvinas. "Given the promising results seen in preclinical studies, it is our hope that ARV-110 will overcome known mechanisms of resistance to standard of care agents and offer a new treatment option for patients. We believe this is the first time a patient has been treated with this new class of targeted protein degraders and we look forward to furthering our understanding of ARV-110 as a potential treatment for men with mCRPC and the broader field of protein degradation."

The Phase 1 open-label, dose-escalation clinical trial will assess the safety, tolerability, and pharmacokinetics of ARV-110 and is expected to enroll approximately 28-36 patients with progressive mCRPC. In addition, the study will evaluate the biochemical and clinical activity of ARV-110, by assessing prostate specific antigen (PSA) levels, AR degradation, radiographic measurements of evaluable lesions, and other exploratory markers of disease burden. Additional information on this clinical trial can be found on www.clinicaltrials.gov.

About Metastatic Castration-Resistant Prostate Cancer (mCRPC)

In the United States, prostate cancer is both the second most prevalent cancer in men and the second leading cause of cancer death in men. The American Cancer Society predicts that one in nine men will be diagnosed with prostate cancer in his lifetime. Metastatic castration-resistant prostate cancer (mCRPC) is defined by disease progression despite androgen deprivation therapy and is often correlated with rising levels of prostate-specific antigen (PSA).

Current AR-targeted standard of care treatments for mCRPC are less effective in patients whose disease has increased levels of androgen production, AR gene or gene enhancer amplification, or AR point mutations. Up to 25% of patients do not respond to second-generation hormone therapies like abiraterone and enzalutamide, and the vast majority of responsive patients will ultimately become resistant, resulting in poor prognoses for men diagnosed with this devastating condition.

About PROTAC™ (Proteolysis-Targeting Chimera) Protein Degraders

Arvinas' PROTAC protein degraders harness the body's own natural protein recycling system to degrade disease-causing proteins. PROTAC protein degraders recruit an E3 ligase to tag the target protein with ubiquitin, which directs its degradation through the proteasome, a large protein complex that breaks down the ubiquitinated target protein into small peptides and amino acids. As the target protein is degraded, the PROTAC™ protein degrader is released and acts iteratively to destroy additional target protein.

PROTAC™ protein degraders offer numerous potential advantages as a therapeutic, including broad tissue distribution, routes of administration that include oral delivery, and simpler manufacturing than other new modalities, such as cell-based therapies. Arvinas has developed and optimized a proprietary library of protein targeting ligands, E3 ligase ligands, and linkers, which allow the company to rapidly identify and optimize efficient protein degraders with favorable characteristics for successful drug development.

About ARV-110

ARV-110 is an orally bioavailable PROTAC™ protein degrader designed to selectively target and degrade the AR. ARV-110 is being developed as a potential treatment for men with mCRPC. ARV-110 has demonstrated activity in preclinical models of AR mutation or overexpression, both common mechanisms of resistance to currently available AR-targeted therapies. Arvinas believes the differentiated pharmacology of ARV-110, including its iterative activity, has the potential to translate into improved clinical outcomes for patients.

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 disposal 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 preliminary data from our clinical trial for ARV-110 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 conduct a Phase 1 clinical trial for ARV-110, complete our clinical trials for our product candidates, and receive results from our clinical trials 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.