Arvinas Receives Fast Track Designation for its Targeted Protein Degrader ARV-110 as a Treatment for Men with Metastatic Castration-Resistant Prostate Cancer

May 29, 2019

ARV-110 is Arvinas' first clinical-stage drug in the innovative field of targeted protein degradation, and is currently being evaluated in a Phase 1 clinical trial

NEW HAVEN, Conn., May 29, 2019 (GLOBE NEWSWIRE) -- Arvinas, Inc. (Nasdaq: ARVN), a biopharmaceutical company creating a new class of therapies that degrades disease-causing proteins, today announced that its lead PROTAC® protein degrader, ARV-110, has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of men with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed after treatment with two or more systemic therapies. ARV-110 is an orally bioavailable PROTAC® protein degrader designed to selectively target and degrade the androgen receptor (AR) protein. ARV-110 is currently being evaluated in a Phase 1 clinical trial designed to evaluate the safety, tolerability, and pharmacokinetics of ARV-110 in men with mCRPC whose disease has progressed after treatment with standard of care therapies.

“While great strides have been made in the treatment of men with metastatic castration-resistant prostate cancer, current AR-targeted standard of care treatments are less effective in patients whose disease includes increased levels of androgen production or mutations in the androgen receptor,” said John Houston, Ph.D., President and Chief Executive Officer of Arvinas. “We believe, due to its ability to iteratively degrade the AR protein, ARV-110 could represent a meaningful new therapy to improve the lives of patients battling mCRPC, and for whom current therapies are not effective. The Fast Track designation by the FDA recognizes the urgency for improved treatments for these patients.”

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. Between 15-25% of patients do not respond to second-generation hormone therapies like abiraterone and enzalutamide, and the majority of responsive patients will ultimately become resistant, resulting in poor prognoses for men diagnosed with this devastating condition.

About PROTAC® Protein Degraders
Arvinas’ PROTAC® protein degraders harness the body’s own natural protein disposal 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 therapeutic advantages, 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 androgen receptor (AR) protein. 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.

The Phase 1 clinical trial of ARV-110, for men with mCRPC whose disease has progressed after treatment with standard of care therapies, began in 1Q2019. Preliminary clinical data for the trial will be shared in 2H2019, including safety, tolerability, and PK data. Full disclosure of trial information is expected in 1H2020, including prostate-specific antigen (PSA) data and Response Evaluation Criteria in Solid Tumors (RECIST) data.

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 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. 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 and full 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.