



Arvinas Presents a Platform Update, Including Initial Data from the First Two Clinical Trials of PROTAC® Targeted Protein Degraders

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-Data from initial cohorts suggest that Arvinas' PROTAC® platform has the potential to create safe and well-tolerated orally bioavailable drugs for the treatment of certain cancers

-Conference call to be held at 8:30 AM ET today

NEW HAVEN, Conn., Oct. 23, 2019 (GLOBE NEWSWIRE) -- Arvinas, Inc., (Nasdaq: ARVN), a biotechnology company creating a new class of drugs based on targeted protein degradation, today announced a platform data update that includes initial safety, tolerability, and pharmacokinetic data from the company's ongoing Phase 1 clinical trials of ARV-110 and ARV-471. The data, which show dose-proportional exposures of ARV-110 and that both ARV-110 and ARV-471 have been well tolerated, will be presented by Ian Taylor, Ph.D., Chief Scientific Officer at Arvinas, at the 2nd Targeted Protein Degradation Summit in Boston, MA. Dr. Taylor's presentation will be available on Arvinas' website this morning.

"This is the first look at clinical data from our PROTAC® platform and is an exciting milestone for both Arvinas and for the field of targeted protein degradation. We are seeing a favorable overall safety profile for both clinical programs to date, and dose-proportional exposures of ARV-110," said John Houston, Ph.D., Chief Executive Officer at Arvinas. "We are encouraged by these initial results as we work to create well tolerated therapies to treat serious diseases."

Phase 1 Study Designs and Clinical Data

Both ARV-110 and ARV-471 are being evaluated in Phase 1, open-label, dose-escalation clinical trials designed to assess safety, tolerability, and pharmacokinetics (PK).

The ARV-110 clinical trial is of 28 to 36 patients with metastatic castration-resistant prostate cancer (mCRPC) who have progressed on at least two prior systemic therapies. The ARV-471 clinical trial is of 24 to 36 patients with estrogen receptor positive (ER+) / human epidermal growth factor receptor-2 negative (HER2-) locally advanced or metastatic breast cancer who have received prior hormonal therapy and chemotherapy.

Both ARV-110 and ARV-471 are oral therapies dosed once per day.

The presentation today will show that Arvinas' PROTAC® protein degraders have been well tolerated by patients at the doses tested to date. The initial data for ARV-110 are from the first three dose-escalation cohorts (35 mg, 3 patients; 70 mg, 4 patients; and 140 mg, 3 patients), while the initial data presented for ARV-471 are from three patients enrolled in the first dose cohort (30 mg). Both ARV-110 (35, 70, and 140 mg) and ARV-471 (30 mg) were well tolerated, with no dose-limiting toxicities (DLTs) and no grade 2, 3, or 4 related adverse events observed.

The presentation today will also show dose proportionality for ARV-110 and that exposures of both ARV-110 and ARV-471 have reached levels associated with tumor growth inhibition in preclinical studies. For both programs and at each dose level tested to date, PK data were evaluated at days 1 and 15 following initial dosing. The third (140 mg) cohort of ARV-110 and the first (30 mg) cohort of ARV-471 reached average plasma exposures and average maximum concentrations that were above the lower ends of the ranges that were associated with tumor growth inhibition in preclinical studies. In addition, increases in exposure and average maximum concentration of ARV-110 were dose-proportional across all three doses tested to date.

For the next cohorts of each of ARV-110 and ARV-471, the dose is being increased by 100% (to 280 mg for ARV-110, and to 60 mg for ARV-471). Aside from continuing to investigate safety and PK, the Phase 1 clinical trial of ARV-110 will also evaluate biochemical and clinical activity by assessing prostate specific antigen (PSA) levels and RECIST response in patients with baseline measurable disease, androgen receptor (AR) degradation, and other exploratory biomarkers. The Phase 1 clinical trial of ARV-471 will continue to evaluate safety and PK, as well as evaluate estrogen receptor (ER) degradation, RECIST response in patients with baseline measurable disease, and other exploratory biomarkers.

Arvinas expects to next share clinical data from the Phase 1 dose escalation trial of ARV-110 in the first half of 2020 and from the Phase 1 dose escalation trial of ARV-471 in the second half of 2020.

Conference Call:

The company will host a conference call and webcast at 8:30 AM ET today to discuss these initial data. Participants are invited to listen by dialing (844) 467-7654 (domestic) or (602) 563-8497 (international) five minutes prior to the start of the call and providing the passcode access code 9096099. A listen-only webcast of the conference call can also be accessed through the "Investors" tab on the Arvinas website, www.arvinas.com, and a replay will be available for six weeks following the call.

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 has two clinical-stage programs: ARV-110 for the treatment of patients with metastatic castrate-resistant prostate cancer; and ARV-471 for the treatment of patients with ER+/HER2- locally advanced or metastatic breast cancer. For more information, visit www.arvinas.com.

About ARV-110

ARV-110 is an orally-bioavailable PROTAC® protein degrader designed to selectively target and degrade the androgen receptor (AR). ARV-110 is being developed as a potential treatment for men with metastatic castration-resistant prostate cancer (mCRPC). Arvinas' Phase 1 trial of ARV-110 will assess its safety, tolerability, and pharmacokinetics, and will also include measures of anti-tumor activity and pharmacodynamic readouts as secondary endpoints.

ARV-110 has demonstrated activity in preclinical models of AR mutation or overexpression, both common mechanisms of resistance to currently available AR-targeted therapies.

About ARV-471

ARV-471 is a PROTAC® protein degrader designed to specifically target and degrade the estrogen receptor (ER) for the treatment of women with metastatic breast cancer. Arvinas' Phase 1 trial of ARV-471 will assess its safety, tolerability, and pharmacokinetics, 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 (as a single agent and in combination with a CDK4/6 inhibitor).

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, such as statements with respect to our lead product candidates, ARV-110 and ARV-471, and the timing of clinical trials and data from those trials for our product candidates, and our discovery programs that may lead to our development of additional product candidates, the potential utility of our technology and advantages and therapeutic potential of our product candidates, and the sufficiency of our cash resources. 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 Phase 1 clinical trials for ARV-110 and ARV-471, complete other 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 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.

Contacts for Arvinas

Investor Relations

Will O'Connor, Stern Investor Relations
ir@arvinas.com

Media

Cory Tromblee, ScientPR
pr@arvinas.com



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