Pfizer Logo

Arvinas and Pfizer Announce Updated Vepdegestrant (ARV-471) Data to be Presented at the 2023 San Antonio Breast Cancer Symposium

Tuesday, November 28, 2023 - 05:05pm

-- Six abstracts have been accepted for presentation, including updated data on vepdegestrant alone and in combination with palbociclib (IBRANCE®) --

NEW HAVEN, Conn. and NEW YORK, November 28, 2023 – Arvinas, Inc. (Nasdaq: ARVN) and Pfizer Inc. (NYSE: PFE) today announced that updated clinical trial data for vepdegestrant (ARV-471) will be presented at the 2023 San Antonio Breast Cancer Symposium (SABCS). Vepdegestrant is a novel oral PROteolysis TArgeting Chimera (PROTAC®) estrogen receptor (ER) degrader currently being investigated for the potential treatment of patients with locally advanced or metastatic estrogen receptor (ER) positive/human epidermal growth factor receptor 2 (HER2) negative (ER+/HER2-) breast cancer. Arvinas and Pfizer are collaborating to develop and commercialize vepdegestrant.

Data from the Phase 1b study assessing vepdegestrant in combination with palbociclib (IBRANCE®) will be presented in a spotlight session on December 7, 2023. An update on the Phase 2 vepdegestrant monotherapy (VERITAC) study will be presented in a poster presentation alongside four other posters during the symposium held from December 5-9, 2023, in San Antonio, Texas.
Session details are as follows in chronological order. For more information, visit the official SABCS website here.

VERITAC-2 Trial in Progress

Poster Session 1 (ID: PO1-19-12)
Wednesday, December 6, 12:00-2:00 PM CT

VERITAC-2: a Phase 3 study of vepdegestrant, a PROteolysis TArgeting Chimera (PROTAC) estrogen receptor (ER) degrader, vs fulvestrant in ER–positive/human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer

Mario Campone

VERITAC-3 Study Lead-in Trial in Progress

Poster Session 2 (ID: PO2-20-03)
Wednesday, December 6, 5:00-7:00 PM CT

VERITAC-3: A randomized Phase 3 study, with a lead-in, of first-line vepdegestrant + palbociclib vs letrozole + palbociclib in estrogen receptor-positive/human epidermal growth factor receptor 2-negative advanced breast cancer

Seth Wander

TACTIVE-U Trial in Progress

Poster Session 2 (ID: PO2-20-04)
Wednesday, December 6, 5:00-7:00 PM CT

TACTIVE-U: Phase 1b/2 umbrella study of vepdegestrant, a PROteolysis TArgeting Chimera (PROTAC) estrogen receptor (ER) degrader, combined with other anticancer treatments in ER–positive advanced or metastatic breast cancer

Claudine Isaacs

Vepdegestrant Monotherapy (VERITAC) Update

Poster Session 3 (ID: PO3-05-08)
Thursday, December 7, 12:00-2:00 PM CT

Updated results from VERITAC evaluating vepdegestrant, a PROteolysis TArgeting Chimera (PROTAC) estrogen receptor (ER) degrader, in ER-positive/human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer

Sara Hurvitz

Vepdegestrant + Palbociclib Phase 1b

Spotlight Session: Novel nuclear receptor targeting therapies (ID: PS15-03)
Thursday, December 7, 5:30-6:30 PM CT

Vepdegestrant, a PROteolysis TArgeting Chimera (PROTAC) estrogen receptor (ER) degrader, plus palbociclib in ER-positive/human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer: phase 1b cohort

Erika Hamilton

Pharmacokinetic/Pharmacodynamic Modeling of Palbociclib

Poster Session 5 (ID: PO5-14-11)
Friday, December 8, 12:00-2:00 PM CT

Leveraging a pharmacokinetic/pharmacodynamic (PK/PD) model to guide dose optimization of palbociclib in combination with Vepdegestrant

Brian Jermain

About vepdegestrant (ARV-471)
Vepdegestrant is an investigational, orally bioavailable PROTAC protein degrader designed to specifically target and degrade the estrogen receptor (ER) for the treatment of patients with ER positive/human epidermal growth factor receptor 2 (HER2) negative (ER+/HER2-) breast cancer.

In preclinical studies, vepdegestrant demonstrated up to 97% ER degradation in tumor cells, induced robust tumor shrinkage when dosed as a single agent in multiple ER-driven xenograft models, and showed increased anti-tumor activity when compared to a standard of care agent, fulvestrant, both as a single agent and in combination with a CDK4/6 inhibitor. In July 2021, Arvinas announced a global collaboration with Pfizer for the co-development and co-commercialization of vepdegestrant; Arvinas and Pfizer will equally share worldwide development costs, commercialization expenses, and profits. Ongoing and planned clinical trials will continue to monitor and evaluate the safety and anti-tumor activity of vepdegestrant.

About Arvinas
Arvinas is a clinical-stage biotechnology 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 PROTAC Discovery Engine 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. In addition to its robust preclinical pipeline of PROTAC protein degraders against validated and "undruggable" targets, the company has three investigational clinical-stage programs: ARV-766 and bavdegalutamide for the treatment of men with metastatic castration-resistant prostate cancer; and vepdegestrant (ARV-471) for the treatment of patients with locally advanced or metastatic ER+/HER2- breast cancer. For more information, visit www.arvinas.com.

Arvinas Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties, including statements regarding the potential advantages and therapeutic benefits of vepdegestrant (ARV-471), as well as other statements with respect to vepdegestrant, including the presentation and/or publication of data from vepdegestrant trials. All statements, other than statements of historical facts, contained in this press release are forward-looking statements. The words "believe," "expect," "may," "plan," "potential," "will," "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: our and Pfizer Inc.'s ("Pfizer") performance of our respective obligations with respect to our collaboration with Pfizer; whether we and Pfizer will be able to successfully conduct and complete clinical development for vepdegestrant and obtain marketing approval for and commercialize vepdegestrant on our current timelines or at all; whether our cash and cash equivalent resources will be sufficient to fund our foreseeable and unforeseeable operating expenses and capital expenditure requirements; and other important factors discussed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2022, and subsequent other 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 after the date of this release.

About IBRANCE® (palbociclib) 125 mg tablets and capsules
IBRANCE is an oral inhibitor of CDKs 4 and 6,ii which are key regulators of the cell cycle that trigger cellular progression.iii,iv In the U.S., IBRANCE is indicated for the treatment of adult patients with HR+, HER2- advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men; or with fulvestrant in patients with disease progression following endocrine therapy.

The full U.S. Prescribing Information for the IBRANCE tablets and the IBRANCE capsules can be found here and here.

IMPORTANT IBRANCE®(palbociclib) SAFETY INFORMATION FROM THE U.S. PRESCRIBING INFORMATION

Neutropenia was the most frequently reported adverse reaction in PALOMA-2 (80%) and PALOMA-3 (83%). In PALOMA-2, Grade 3 (56%) or 4 (10%) decreased neutrophil counts were reported in patients receiving IBRANCE plus letrozole. In PALOMA-3, Grade 3 (55%) or Grade 4 (11%) decreased neutrophil counts were reported in patients receiving IBRANCE plus fulvestrant. Febrile neutropenia has been reported in 1.8% of patients exposed to IBRANCE across PALOMA-2 and PALOMA-3. One death due to neutropenic sepsis was observed in PALOMA-3. Inform patients to promptly report any fever.
Monitor complete blood count prior to starting IBRANCE, at the beginning of each cycle, on Day 15 of first 2 cycles and as clinically indicated. Dose interruption, dose reduction, or delay in starting treatment cycles is recommended for patients who develop Grade 3 or 4 neutropenia.

Severe, life-threatening, **or fatal interstitial lung disease (ILD) and/or pneumonitis** can occur in patients treated with CDK4/6 inhibitors, including IBRANCE when taken in combination with endocrine therapy. Across clinical trials (PALOMA-1, PALOMA-2, PALOMA-3), 1.0% of IBRANCE-treated patients had ILD/pneumonitis of any grade, 0.1% had Grade 3 or 4, and no fatal cases were reported. Additional cases of ILD/pneumonitis have been observed in the post-marketing setting, with fatalities reported.

Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis (e.g. hypoxia, cough, dyspnea). In patients who have new or worsening respiratory symptoms and are suspected to have developed pneumonitis, interrupt IBRANCE immediately and evaluate the patient. Permanently discontinue IBRANCE in patients with severe ILD or pneumonitis.

Based on the mechanism of action, IBRANCE can cause fetal harm. Advise females of reproductive potential to use effective contraception during IBRANCE treatment and for at least 3 weeks after the last dose. IBRANCE may **impair fertility in males** and has the potential to cause genotoxicity. Advise male patients to consider sperm preservation before taking IBRANCE. Advise male patients with female partners of reproductive potential

to use effective contraception during IBRANCE treatment and for 3 months after the last dose. Advise females to inform their healthcare provider of a known or suspected pregnancy. Advise women not to breastfeed during IBRANCE treatment and for 3 weeks after the last dose because of the potential for serious adverse reactions in nursing infants.

The most common adverse reactions(?10%) of any grade reported in **PALOMA-2** for IBRANCE plus letrozole vs placebo plus letrozole were neutropenia (80% vs 6%), infections (60% vs 42%), leukopenia (39% vs 2%), fatigue (37% vs 28%), nausea (35% vs 26%), alopecia (33% vs 16%), stomatitis (30% vs 14%), diarrhea (26% vs 19%), anemia (24% vs 9%), rash (18% vs 12%), asthenia (17% vs 12%), thrombocytopenia (16% vs 1%), vomiting (16% vs 17%), decreased appetite (15% vs 9%), dry skin (12% vs 6%), pyrexia (12% vs 9%), and dysgeusia (10% vs 5%).
The **most frequently reported Grade ?3 adverse reactions (?5%)** in **PALOMA-2** for IBRANCE plus letrozole vs placebo plus letrozole were neutropenia (66% vs 2%), leukopenia (25% vs 0%), infections (7% vs 3%), and anemia (5% vs 2%).

Lab abnormalities of any grade occurring in **PALOMA-2** for IBRANCE plus letrozole vs placebo plus letrozole were decreased WBC (97% vs 25%), decreased neutrophils (95% vs 20%), anemia (78% vs 42%), decreased platelets (63% vs 14%), increased aspartate aminotransferase (52% vs 34%), and increased alanine aminotransferase (43% vs 30%).

The **most common adverse reactions (?10%)** of any grade reported in **PALOMA-3** for IBRANCE plus fulvestrant vs placebo plus fulvestrant were neutropenia (83% vs 4%), leukopenia (53% vs 5%), infections (47% vs 31%), fatigue (41% vs 29%), nausea (34% vs 28%), anemia (30% vs 13%), stomatitis (28% vs 13%), diarrhea (24% vs 19%), thrombocytopenia (23% vs 0%), vomiting (19% vs 15%), alopecia (18% vs 6%), rash (17% vs 6%), decreased appetite (16% vs 8%), and pyrexia (13% vs 5%).

The most frequently reported Grade ?3 adverse reactions (?5%) in **PALOMA-3** for IBRANCE plus fulvestrant vs placebo plus fulvestrant were neutropenia (66% vs 1%) and leukopenia (31% vs 2%).
Lab abnormalities of any grade occurring in **PALOMA-3** for IBRANCE plus fulvestrant vs placebo plus fulvestrant were decreased WBC (99% vs 26%), decreased neutrophils (96% vs 14%), anemia (78% vs 40%), decreased platelets (62% vs 10%), increased aspartate aminotransferase (43% vs 48%), and increased alanine aminotransferase (36% vs 34%).

Avoid concurrent use of strong **CYP3A inhibitors**. If patients must be administered a strong CYP3A inhibitor, reduce the IBRANCE dose to 75 mg. If the strong inhibitor is discontinued, increase the IBRANCE dose (after 3-5 half-lives of the inhibitor) to the dose used prior to the initiation of the strong CYP3A inhibitor. Grapefruit or grapefruit juice may increase plasma concentrations of IBRANCE and should be avoided. Avoid concomitant use of **strong CYP3A inducers**. The dose of **sensitive CYP3A substrates** with a narrow therapeutic index may need to be reduced as IBRANCE may increase their exposure.

For patients with **severe hepatic impairment** (Child-Pugh class C), the recommended dose of IBRANCE is 75 mg. The pharmacokinetics of IBRANCE have not been studied in patients **requiring hemodialysis.**

About Pfizer Oncology
At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference in the lives of people living with cancer. Today, we have an industry-leading portfolio of 24 approved innovative cancer medicines and biosimilars across more than 30 indications, including breast, genitourinary, colorectal, blood and lung cancers, as well as melanoma.

About Pfizer: Breakthroughs That Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice:
The information contained in this release is as of November 28, 2023. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about vepdegestrant (ARV-471), IBRANCE® (palbociclib) and a global collaboration between Pfizer and Arvinas to develop and commercialize ARV-471, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of IBRANCE; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when any applications may be filed in any jurisdictions for ARV-471 for any potential indications or any other potential indications for IBRANCE; whether and when regulatory authorities may approve any potential applications that may be filed for ARV-471 and IBRANCE in any jurisdictions, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether such product will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of ARV-471 and IBRANCE; whether the collaboration between Pfizer and Arvinas will be successful; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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