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A Study to Learn About a New Medicine Called Vepdegestrant (ARV-471, PF-07850327) in People Who Have Advanced Metastatic Breast Cancer (VERITAC-2)

Pfizer

Status and phase

Active, not recruiting Phase 3

Conditions

Advanced Breast Cancer

Treatments

Drug: ARV-471 Drug: Fulvestrant

Study type

Interventional

Funder types

Industry

Identifiers

NCT05654623
C4891001
2022-500544-38-00 (Other Identifier)

Take notes

View 447 locations

Contact trial

Timeline

Last updated: Mar 13, 2025

Start date
Mar 03, 2023 • 2 years ago

End date
Jan 31, 2025 • 1 month ago

Today

Sponsors of this trial

Lead Sponsor

Pfizer

Collaborating Sponsor

Arvinas

Details and patient eligibility

Full description

The purpose of this study is to learn about the safety and effects of the study medicine ARV-471 (PF-07850327, vepdegestrant) compared to fulvestrant (FUL) in participants with advanced breast cancer. Advanced breast cancer is difficult to cure or control with treatment. The cancer may have spread from where it first started to nearby tissue, lymph nodes, or distant parts of the body, i.e. bones, lungs, brain, or liver. FUL is a medicine already used for treatment of breast cancer while ARV-471 is a new medicine.

This study is seeking participants with breast cancer who:

- have cancer that has come back in the place where it started or spread to nearby tissue, lymph nodes, or distant parts of the body.
- cannot be fully cured by surgery or radiation therapy. Radiation therapy is the use of high-energy radiation such as x-rays, gamma rays and other sources to kill cancer cells and shrink tumors.
- respond to hormonal or endocrine therapy (which target hormones and/or activity of hormone receptors) such as tamoxifen or aromatase inhibitors (this is called estrogen receptor positive disease)
- have received one line of CDK4/6 inhibitor therapy (for example palbociclib, ribociclib or abemaciclib) in combination with endocrine therapy (for example letrozole) for advanced cancer.
- are allowed up to one other endocrine therapy (for example exemestane) for advanced cancer.

Half of the participants will be given ARV-471 while the other half of the participants will be given FUL.

Participants who get ARV-471 will take ARV-471 by mouth with food, one time a day. During the first treatment cycle participants who will get FUL will be given FUL by shots into the muscles on Day 1 and again 2 weeks later. After the first month, FUL shots will be given on the first day of each new treatment cycle. One treatment cycle is 28 days.

Participants will receive the study medicine until their breast cancer worsens or side effects become too severe. Participants will have visits at the study clinic about every 4 weeks.

Hide

Enrollment	**Sex**
624 patients	All
Ages	**Volunteers**
18+ years old	No Healthy Volunteers

Inclusion criteria

- Adult participants with loco-regional recurrent or metastatic breast disease not amenable to surgical resection or radiation therapy
- Confirmed diagnosis of ER+/HER2- breast cancer
- Prior therapies for locoregional recurrent or metastatic disease must fulfill all the following criteria:

to disease progression. This may be the endocrine treatment component of the CDK4/6 inhibitor line of therapy.
- Radiological progression during or after the last line of therapy.
- Measurable disease evaluable per Response Evaluation Criterion in Solid Tumors (RECIST) v.1.1 or non-measurable bone-only disease
- Eastern Cooperative Oncology Group (ECOG) performance status 0-1
- Participants should be willing to provide blood and tumor tissue

Exclusion criteria

- Participants with advanced, symptomatic visceral spread, that are at risk of life-threatening complications in the short term
- Prior treatment with:
- ARV-471, fulvestrant, elacestrant, mTOR, PI3K, AKT pathway inhibitors, PARP inhibitor for any setting
- other investigational agents (including novel endocrine therapy any SERDs, SERCAs, CERANs) for any setting
- prior chemotherapy for advanced/metastatic disease
- Inadequate liver, kidney and bone marrow function
- Active brain metastases
- Participants with significant concomitant illness

Trial design

Primary purpose

Treatment

Allocation

Randomized

Interventional model

Parallel Assignment

Masking

None (Open label)

624 participants in 2 patient groups

ARV-471

Experimental group

Treatment:
Drug: ARV-471

Fulvestrant

Active comparator group

Treatment:

Trial contacts and locations 447

All locations

Sunshine Coast University Private Hospital | Clinical Trials
Veeva-enabled site

3 Doherty street, Birtinya, Queensland 4575

Not yet enrolling

BRCR Medical Center | Plantation, FL
Veeva-enabled site

8200 W Sunrise Boulevard Suite D1 -D2, Plantation, Florida 33322

Enrolling

Contact site

EP-SOGO Co., Ltd. | Nagoya City University Hospital
Veeva-enabled site

Mizuho-ku,Kawasumi 1, Nagoya, Aichi 467-8602

Enrolling

Rajiv Gandhi Cancer Institute and Research Centre | Clinical Research (Dr D.C.Doval)
Veeva-enabled site

D-18, Sector 5, Rohini, New Delhi, Delhi 110085

Enrolling

Comprehensive Cancer Centers of Nevada | Las Vegas, NV
Veeva-enabled site

3920 S Eastern Avenue, Suite 202, Las Vegas, Nevada 89119

Enrolling

View more

Central trial contact

Pfizer CT.gov Call Center

Contact trial

Combination Followed by Maintenance Chemotherapy Versus CDK4/6 Inhibitor Combin...

Henan Cancer Hospital

Enrolling

Treatment

Zhengzhou, Henan, China

Safety of Elacestrant in ER+/HER2- and ESR1 Mutations MBC

SciClone Pharmaceuticals

Enrolling

ESR1 Gene Mutation

Qionghai, Hainan, China

Dalpiciclib With Endocrine Therapy for Advanced Breast Cancer After CDK4/6 Inhi...

Chinese Academy of Medical Sciences & Peking Union Medical College

Enrolling

Advanced Breast Cancer

Beijing, Beijing, China

Data sourced from clinicaltrials.gov