VERITAC-2

2L MBC MONO TRIAL

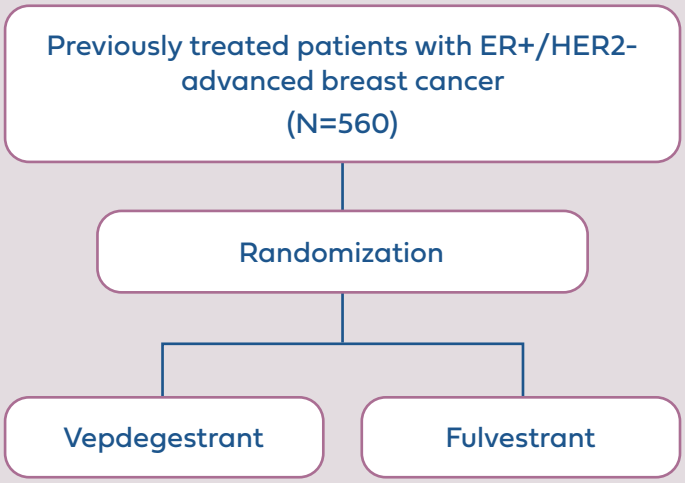
Vepdegestrant (ARV-471)

NOW ENROLLING

A Phase 3, Randomized, Open-Label Study of Vepdegestrant (ARV-471) vs Fulvestrant in Patients With ER+/HER2- Advanced Breast Cancer

Vepdegestrant is an investigational compound and is not approved for any use. Its safety and efficacy have not been established.

Trial Schema



This information is current as of August 2023

Key Eligibility Criteria[a]

Inclusion Criteria

- Women or men aged ≥18 years
- Confirmed ER+/HER2- locoregional recurrent or metastatic breast cancer
- Prior therapies for locoregional recurrent or metastatic disease must fulfill all the following criteria:
  - 1 line of CDK4/6 inhibitor therapy in combination with endocrine therapy (only 1 line of CDK4/6 inhibitor in any setting)
  - ≤1 endocrine therapy in addition to CDK4/6 inhibitor with endocrine therapy
  - Most recent endocrine treatment given for ≥6 months prior to disease progression
  - Radiological progression during or after the last line of therapy
- ECOG performance status of 0 or 1
- Measurable disease evaluable per RECIST v.1.1 or nonmeasurable bone-only disease

Exclusion Criteria

- Active brain metastases
- Advanced, symptomatic visceral spread at risk of life threatening complications in the short term
- Prior treatment with vepdegestrant; fulvestrant; elacestrant; mTOR, PI3K, or AKT pathway inhibitors; PARP inhibitors; other investigational agents including novel endocrine therapy (SERDs, SERCAs, CERANs); or chemotherapy for advanced/metastatic disease

Summary of Endpoints

Primary

- Progression-free survival by blinded independent central review

Secondary

- Overall survival
- ORR,[b] DOR, and CBR[c]
- Incidence of AEs, SAEs, and ECG and laboratory abnormalities
- QT interval
- Plasma concentration-time of vepdegestrant
- QoL measurements
- Circulating tumor DNA changes

[a]This is not the complete list of inclusion/exclusion criteria. [b]ORR refers to proportion of patients with confirmed complete response or partial response by blinded independent central review. [c]CBR refers to proportion of patients with confirmed complete response, partial response, or stable disease ≥24 weeks by blinded independent central review.

AE=adverse event; AKT=protein kinase B; CBR=clinical benefit rate; CDK4/6=cyclin-dependent kinase 4 and 6; CERAN=complete estrogen receptor antagonist; DOR=duration of response; ECG=electrocardiogram; ECOG=Eastern Cooperative Oncology Group; ER=estrogen receptor; HER2=human epidermal growth factor receptor 2; mTOR=mammalian target of rapamycin; ORR=objective response rate; PARP=poly adenosine diphosphate ribose polymerase; PI3K=phosphoinositide-3 kinase; QoL=quality of life; RECIST=Response Evaluation Criteria in Solid Tumors; SAE=serious adverse event; SERCA=selective estrogen receptor covalent antagonist; SERD=selective estrogen receptor degrader.

For additional protocol details, please visit www.clinicaltrials.gov (NCT05654623)

Pfizer ARVINAS

 MED-US-471-2200005