# VERITAC-3

1L MBC COMBO TRIAL

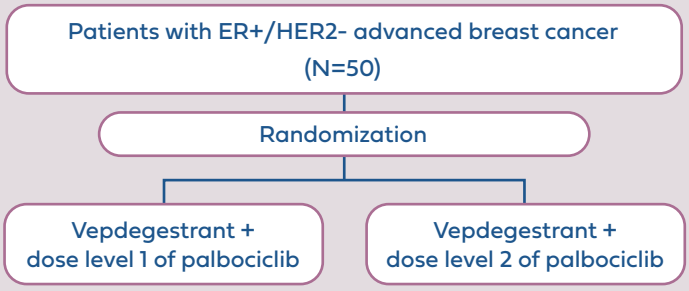
Vepdegestrant (ARV-471)

# NOW ENROLLING

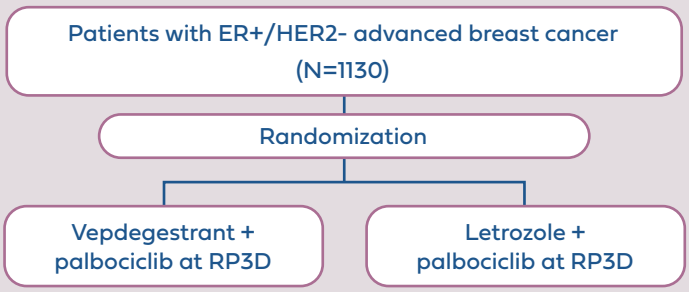
## A Phase 3, Randomized, Open-Label Study of Vepdegestrant (ARV-471) Plus Palbociclib vs Letrozole Plus Palbociclib in Patients With ER+/HER2- Advanced Breast Cancer

Vepdegestrant is an investigational compound. Its safety and efficacy have not been established. The combination of vepdegestrant and palbociclib has not been approved for any use.

### Trial Schema: Study Lead-in to Identify RP3D of Palbociclib in Combination With Vepdegestrant




### Trial Schema: Phase 3




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
- No prior systemic treatment for locoregional recurrent or metastatic disease
- ECOG performance status of 0–2
- Measurable disease evaluable per RECIST v.1.1 or nonmeasurable bone-only disease

### Exclusion Criteria

- Prior treatment with CDK4/6 inhibitors, SERDs, CERANs, SERCAs, or investigational agents
- Disease recurrence while on or within 12 months of completion of adjuvant endocrine therapy

## Summary of Endpoints

| | Study lead-in | Phase 3 |
|---|---|---|
| **Primary** | • Incidence of grade 4 neutropenia, study drug dose reduction, and study drug discontinuation in the first 4 cycles | • PFS by blinded independent central review |
| **Secondary** | • ORR,[b] DOR, and CBR[c]<br>• Incidence of AEs, SAEs, and ECG and laboratory abnormalities<br>• Plasma concentrations of vepdegestrant and palbociclib | • ORR,[b] DOR, CBR,[c] and OS<br>• Incidence of AEs, SAEs, and ECG and laboratory abnormalities<br>• Plasma concentrations of vepdegestrant and palbociclib<br>• QoL measurements<br>• 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. [c]CBR refers to proportion of patients with complete response, partial response, or stable disease ≥24 weeks.

AE=adverse event; 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; ORR=objective response rate; OS=overall survival; PFS=progression-free survival; QoL=quality of life; RECIST=Response Evaluation Criteria in Solid Tumors; RP3D=recommended phase 3 dose; SAE=serious adverse event; SERCA=selective estrogen receptor covalent antagonist; SERD=selective estrogen receptor degrader.

For additional protocol details, please visit www.clinicaltrials.gov (NCT05909397)

Pfizer ARVINAS

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