VERITAC-3

1L MBC COMBO TRIAL

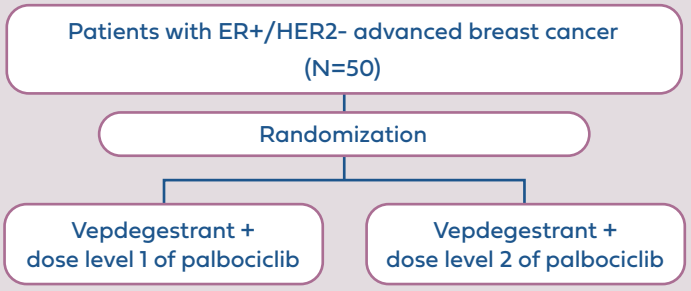
Vepdegestrant (ARV-471)

NOW ENROLLING

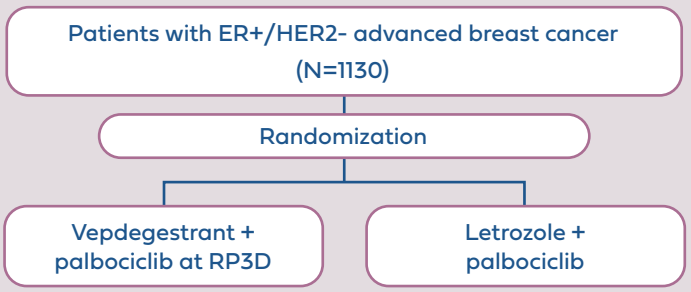
A Phase 3, Randomized, Open-Label Study of Vepdegestrant (ARV-471) Plus Palbociclib vs Letrozole Plus Palbociclib in Patients With ER+/HER2- Advanced Breast Cancer

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 May 2024

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 Outcome Measures

	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] • Safety and tolerabilty • Plasma concentrations of vepdegestrant and palbociclib	• ORR,[b] DOR, CBR,[c] and OS • Safety and tolerabilty • Plasma concentrations of vepdegestrant and palbociclib • 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. [c]CBR refers to proportion of patients with complete response, partial response, or stable disease ≥24 weeks.

CBR=clinical benefit rate; CDK4/6=cyclin-dependent kinase 4 and 6; CERAN=complete estrogen receptor antagonist; DOR=duration of response; 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; 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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