Tactive-U
UMBRELLA TRIAL

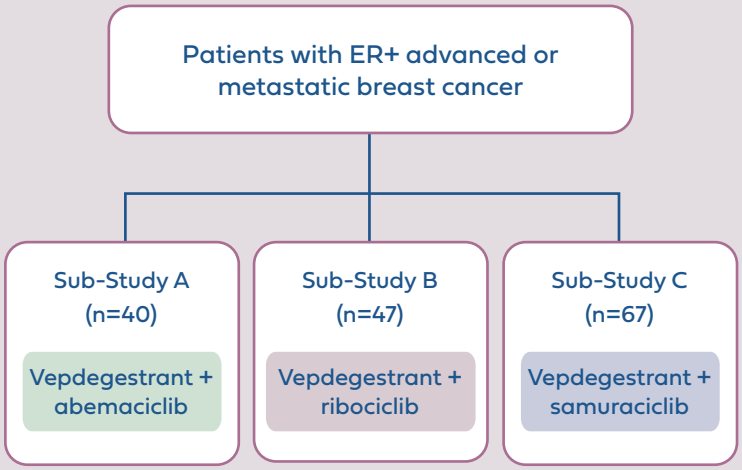
Vepdegestrant (ARV-471)

NOW ENROLLING:
Sub-Studies A, B, and C

A Phase 1b/2 Umbrella Study of Vepdegestrant (ARV-471) in Combination With Other Anticancer Treatments in Patients With ER+ Advanced or Metastatic Breast Cancer

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

Trial Schema



This information is current as of March 2024

Key Eligibility Criteria[a]

Inclusion Criteria

- Women or men aged ≥18 years
- Histologically or cytologically confirmed ER+/HER2- advanced or metastatic breast cancer not amenable to surgical resection with curative intent
- Up to 2 lines of prior therapy for advanced or metastatic disease
  - 1 line of any CDK4/6 inhibitor–based regimen in any setting is required
- ECOG performance status of 0 or 1
- ≥1 measurable lesion as defined by RECIST v1.1

Exclusion Criteria

- Newly diagnosed brain metastases or symptomatic CNS metastases, carcinomatous meningitis, or leptomeningeal disease
- Inflammatory breast cancer
- Visceral crisis at risk of life-threatening complications in the short term

Summary of Key Endpoints[b]

	Phase 1b	Phase 2
Primary	• DLTs	• ORR[c]
Secondary	• ORR,[c] CBR,[d] DOR, and PFS • Type, frequency, and severity of AEs[e] and laboratory abnormalities • Plasma concentrations of study drugs	• CBR,[d] DOR, PFS, and OS • Type, frequency, and severity of AEs[e] and laboratory abnormalities • Plasma concentrations of study drugs • Circulating tumor DNA changes • *TP53* mutation status (Sub-Study C)

[a]This is not the complete list of inclusion/exclusion criteria. [b]This is not the complete list of endpoints, and individual sub-studies may have additional outcome measures. [c]ORR refers to proportion of patients with confirmed complete response or partial response. [d]CBR refers to proportion of patients with confirmed complete response, partial response, or stable disease ≥24 weeks. [e]Including serious AEs and treatment-related serious AEs.

AE=adverse event; CBR=clinical benefit rate; CDK4/6=cyclin-dependent kinase 4 and 6; CNS=central nervous system; DLT=dose-limiting toxicity; 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; RECIST v1.1=Response Evaluation Criteria in Solid Tumors version 1.1; *TP53*=tumor protein p53.

Sub-Study A | Sub-Study B | Sub-Study C

For additional protocol details, please visit www.clinicaltrials.gov
(Sub-Study A; NCT05548127)
(Sub-Study B; NCT05573555)
(Sub-Study C; NCT06125522)

Pfizer ARVINAS