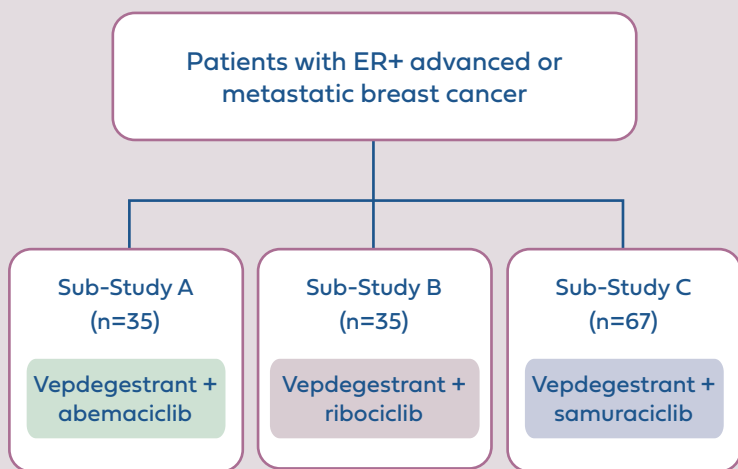


NOW ENROLLING: Sub-Studies A, B, and C

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



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

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 Endpoints

	Phase 1b	Phase 2
Primary	• DLTs	• ORR ^b
Secondary	<ul style="list-style-type: none"> • ORR,^b CBR,^c DOR, and PFS • Type, frequency, and severity of AEs and laboratory abnormalities • Plasma concentrations of study drugs 	<ul style="list-style-type: none"> • CBR,^c DOR, PFS, and OS • Type, frequency, and severity of AEs and laboratory abnormalities • Plasma concentrations of study drugs • Circulating tumor DNA changes • TP53 mutation status (Sub-Study C)

^aThis is not the complete list of inclusion/exclusion criteria. ^bORR refers to proportion of patients with confirmed complete response or partial response. ^cCBR refers to proportion of patients with confirmed complete response, partial response, or stable disease ≥ 24 weeks.

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; TP53=tumor protein p53.

This information is current as of November 2023



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)

