Tactive-K

VEPDEGESTRANT + PF-07220060
(A CDK4 INHIBITOR) TRIAL

Vepdegestrant
(ARV-471)

NOW ENROLLING

A Phase 1b/2 Open-Label Study of Vepdegestrant (ARV-471) in Combination With PF-07220060 (a CDK4 Inhibitor) in Patients With ER+/HER2- Advanced or Metastatic Breast Cancer

Vepdegestrant and PF-07220060 are investigational compounds. Their safety and efficacy have not been established. The combination of vepdegestrant and PF-07220060 is not approved for any use.

Trial Schema: Phase 1b Dose Escalation

Previously treated patients with ER+/HER2- advanced breast cancer

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Dose escalation to identify RP2D of the combination of vepdegestrant and PF-07220060

Trial Schema: Phase 2

Previously treated patients with ER+/HER2- advanced breast cancer

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Vepdegestrant in combination with PF-07220060 at RP2D

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- breast cancer not amenable to surgical resection with curative intent
- ≥1 line of prior standard of care therapy (Phase 1b) or 1–2 lines of prior endocrine therapy for >6 months (Phase 2) for advanced or metastatic disease
  - 1 line of prior CDK4/6 inhibitor-based regimen in any setting required (Phase 2)
- ≥1 measurable lesion as defined by RECIST v1.1 (Phase 2)
- ECOG performance status of 0–1 (Phase 1b) or 0–2 (Phase 2)

Exclusion Criteria

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

Summary of Endpoints

	Phase 1b	Phase 2
Primary	• DLTs	• ORR[b]
Secondary	• ORR,[b] DOR, CBR,[c] and PFS • Type, frequency, and severity of AEs, SAEs, treatment-related AEs, treatment-related SAEs, and laboratory abnormalities • ECG parameters • Plasma concentrations of vepdegestrant and PF-07220060 • Pharmacokinetic parameters of vepdegestrant and PF-07220060	• DOR, CBR,[c] and PFS • Type, frequency, and severity of AEs, SAEs, treatment-related AEs, treatment-related SAEs, and laboratory abnormalities • ECG parameters • Plasma concentrations of vepdegestrant and PF-07220060 • 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 confirmed complete response, partial response, or stable disease ≥24 weeks.

AE=adverse event; CBR=clinical benefit rate; CDK=cyclin-dependent kinase; CNS=central nervous system; DLT=dose-limiting toxicity; 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; PFS=progression-free survival; RECIST v1.1=Response Evaluation Criteria in Solid Tumors version 1.1; RP2D=recommended phase 2 dose; SAE=serious adverse event.

For additional protocol details, please visit www.clinicaltrials.gov (NCT06206837)

Pfizer ARVINAS