

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 effectiveness 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

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

Vepdegestrant in combination with PF-07220060 at RP2D

This information is current as of November 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 ET (most recent ET-based treatment 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 Outcome Measures

	Phase 1b	Phase 2
Primary	• DLTs	• ORR ^b
Secondary	• ORR, ^b DOR, CBR, ^c and PFS • Safety and tolerability • Plasma concentrations of vepdegestrant and PF-07220060 • Pharmacokinetic parameters of vepdegestrant and PF-07220060	• DOR, CBR, ^c and PFS • Safety and tolerability • Plasma concentrations of vepdegestrant and PF-07220060 • Circulating tumor DNA changes

^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.

CBR=clinical benefit rate; CDK=cyclin-dependent kinase; CNS=central nervous system; DLT=dose-limiting toxicity; DOR=duration of response; ECOG=Eastern Cooperative Oncology Group; ER=estrogen receptor; ET=endocrine therapy; 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.



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

