ARV-806-101

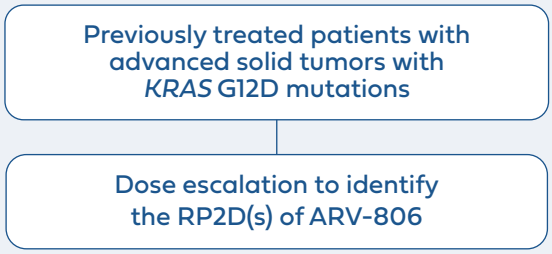
ARV-806

NOW ENROLLING

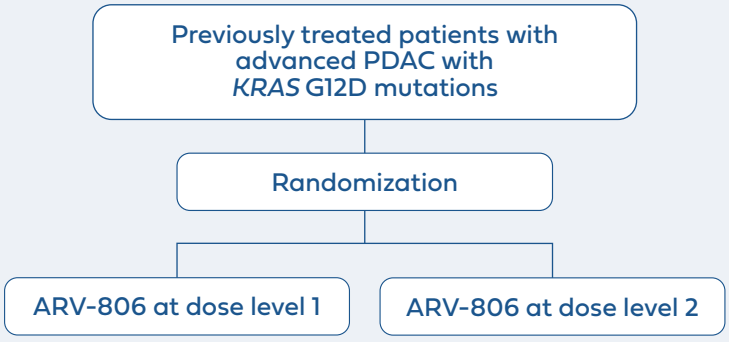
A Phase 1/2 Study of ARV-806 in Patients With *KRAS* G12D–Mutated Advanced Solid Tumors

ARV-806 is an investigational compound and is not approved for any use. Its safety and efficacy have not been established.

Trial Schema: Phase 1 Dose Escalation



Trial Schema: Phase 2 Cohort Expansion



This information is current as of June 2025.

Key Eligibility Criteria[a]

Inclusion Criteria

- Men or women aged ≥18 years
- ≥1 prior line of standard of care therapy
- ≥1 measurable lesion
- ECOG performance status of 0 or 1
- **Phase 1 Dose Escalation**
  - Histologically or cytologically confirmed unresectable or metastatic solid tumor malignancy
  - Evidence of *KRAS* G12D mutation in tumor tissue or blood (ctDNA)
- **Phase 2 Cohort Expansion**
  - Histologically or cytologically confirmed unresectable or metastatic PDAC
  - *KRAS* G12D mutation confirmed by local tumor testing using validated molecular or NGS testing

Exclusion Criteria

- Active brain metastases or carcinomatous meningitis
- Prior treatment with a KRAS G12D– or a KRAS G12C–targeting therapy, including pan-KRAS inhibitors or degraders

Summary of Outcome Measures

	Phase 1	Phase 2
Primary	• DLTs • Safety and tolerability	• ORR[b]
Secondary	• Pharmacokinetic parameters of ARV-806 • ORR[b], TTR, DOR, and DCR[c]	• Safety and tolerability • Pharmacokinetic parameters of ARV-806 • TTR, DOR, and DCR[c]

[a]This is not the complete list of inclusion/exclusion criteria.
[b]The proportion of participants achieving a complete response or partial response.
[c]The proportion of participants achieving a complete response, partial response, or stable disease.

ctDNA=circulating tumor DNA; DCR=disease control rate; DLT=dose-limiting toxicity; DOR=duration of response; ECOG=Eastern Cooperative Oncology Group; KRAS=Kirsten rat sarcoma virus; NGS=next-generation sequencing; ORR=objective response rate; PDAC=pancreatic ductal adenocarcinoma; RP2D=recommended phase 2 dose; TTR=time to response.

For additional protocol details, please visit www.clinicaltrials.gov (NCT07023731)

ARVINAS

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