ARV-766-mCRPC-101

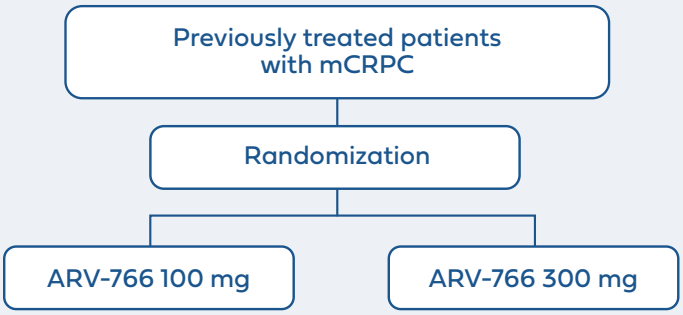
ARV-766

NOW ENROLLING

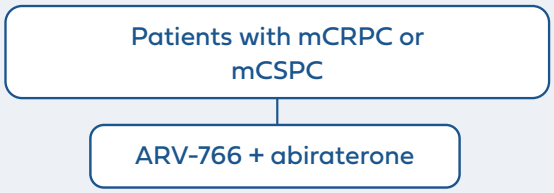
A Phase 1/2 Open-Label Study of ARV-766 in Patients With Metastatic Prostate Cancer

ARV-766 is an investigational compound and is not approved for any use. Its safety and efficacy have not been established.

Trial Schema: Part B (Phase 2 Expansion)



Trial Schema: Part C/D (Combination Dose Escalation and Expansion)



This information is current as of May 2024.

Key Eligibility Criteria[a]

Inclusion Criteria

- Men aged ≥18 years
- Histologically, pathologically, or cytologically confirmed diagnosis of adenocarcinoma of the prostate
- ECOG performance status of 0 or 1
- Additional criteria:
  - Part B (Phase 2 Cohort Expansion): Progressive mCRPC, 1-3 prior NHAs, and ≤2 prior chemotherapy regimens
  - Part C/D (Combination Dose Escalation and Expansion): mCRPC or mCSPC and no prior treatment on NHA

Exclusion Criteria

- Symptomatic brain metastases requiring steroids above physiologic replacement doses
- Active inflammatory gastrointestinal disease, chronic diarrhea, diverticular disease, or previous gastric resection or lap band surgery

Summary of Outcome Measures

Study Part	Primary
Part B (Phase 2 Cohort Expansion)	• PSA response
Part C (Combination Dose Escalation)	• DLTs • Safety and tolerability
Part D (Combination Dose Expansion)	• PSA response

[a]This is not the complete list of inclusion/exclusion criteria.

DLT=dose-limiting toxicity; ECOG=Eastern Cooperative Oncology Group; mCRPC=metastatic castration-resistant prostate cancer; mCSPC=metastatic castration-sensitive prostate cancer; NHA=novel hormonal agent; PSA=prostate-specific antigen.

For additional protocol details, please visit www.clinicaltrials.gov (NCT05067140)

ARVINAS

 MED-US-766-2300003