

# ARV-766-mCRPC-101

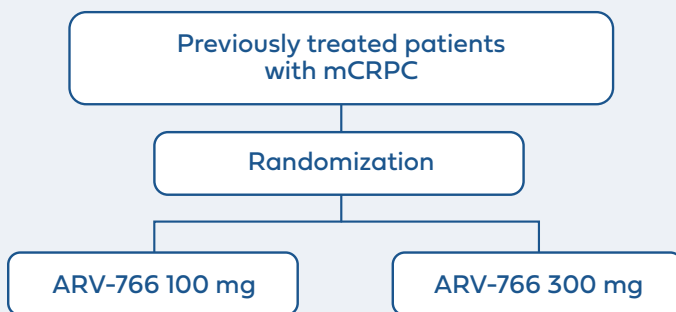
# ARV-766

## NOW ENROLLING

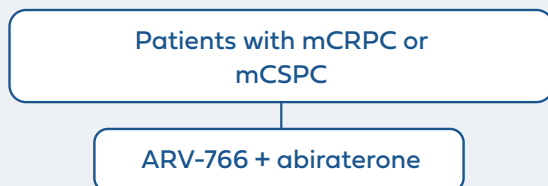
### A Phase 1/2 Open-Label Study of ARV-766 in Patients With Metastatic Prostate Cancer

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)



## Key Eligibility Criteria<sup>a</sup>

### Inclusion Criteria

- Men aged  $\geq 18$  years
- Histologically, pathologically, or cytologically confirmed diagnosis of adenocarcinoma of the prostate
- Ongoing androgen deprivation therapy with a gonadotropin-releasing hormone analog or inhibitor, or orchiectomy (surgical or medical castration)
- ECOG performance status of 0 or 1
- Additional criteria:
  - Part A (Phase 1 Cohort Escalation)<sup>b</sup>: Progressive mCRPC and progression on  $\geq 2$  prior approved systemic therapies (including  $\geq 1$  NHA)
  - Part B (Phase 2 Cohort Expansion): Progressive mCRPC, 1-3 prior NHAs, and  $\leq 2$  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 Endpoints

Sub-Study	Primary
Part A (Phase 1 Dose Escalation) <sup>b</sup>	<ul style="list-style-type: none"> <li>• DLTs</li> <li>• Safety</li> </ul>
Part B (Phase 2 Cohort Expansion)	<ul style="list-style-type: none"> <li>• PSA response</li> </ul>
Part C (Combination Dose Escalation)	<ul style="list-style-type: none"> <li>• DLTs</li> <li>• Safety</li> </ul>
Part D (Combination Dose Expansion)	<ul style="list-style-type: none"> <li>• PSA response</li> </ul>

<sup>a</sup>This is not the complete list of inclusion/exclusion criteria. <sup>b</sup>Part A is closed for enrollment.

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.

This information is current as of January 2024



For additional protocol details, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT05067140)

