
**PROTOCOL TITLE**

ROAD; Real-World Outcomes of Darolutamide, ADT, with or without Docetaxel in Metastatic Hormone Sensitive Prostate Cancer

| ALIAS | CTO NUMBER | SPONSOR |
|---|---|---|
| ROAD | CTO25078BAY | BAYER |

**KEY INCLUSION AND EXCLUSION CRITERIA**

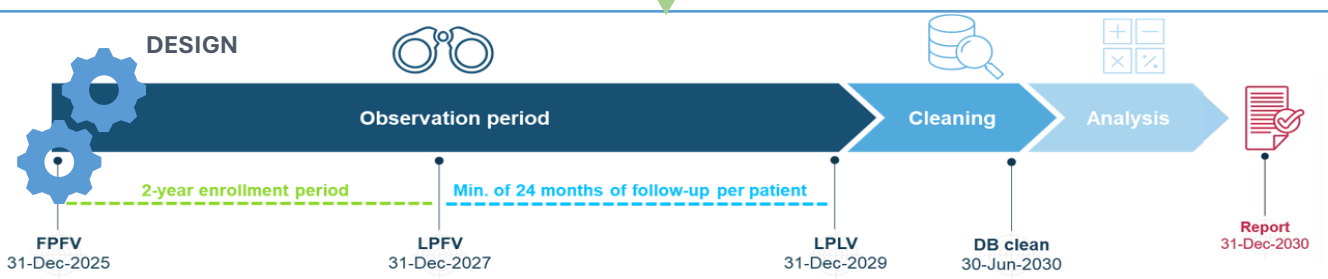
**Inclusion;**

-Histologically or cytologically confirmed adenocarcinoma of prostate. Participants may have begun ADT (up to 120 days prior to enrollment)
-Metastatic disease by conventional or new generation imaging
-Decision to initiate treatment with darolutamide with, or without docetaxel was made as per investigator's routine treatment practice prior to enrollment in the study
-Life expectancy of ≥3 months based on clinical judgment

**Exclusion;**

-Contra-indications according to the local marketing authorization
-Any prior treatment with second-generation AR inhibitors such as enzalutamide, apalutamide, or other investigational AR inhibitors, cytochrome P17 enzyme inhibitor such as abiraterone acetate or other investigational CYP 17 as antineoplastic treatment for prostate cancer
-Prior hormone therapy in the metastatic setting
-Treatment with darolutamide initiated more than 7 days prior to enrollment

**DESIGN**




**Interim analysis (IA) will be performed at the following enrollment milestones:**

- IA 1 per cohort after 200 patients have completed ≥ 12 months of treatment or discontinued treatment.
- IA 2 per cohort after 400 patients have completed ≥ 12 months of treatment or discontinued treatment.
- IA 3 per cohort after 600 patients have completed ≥ 12 months of treatment or discontinued treatment.

*The various reviews may be combined if they are expected to occur within approximately 1 month of each other.*

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