Research Area:

Prostate Cancer

AMG 509

Amgen Study ID Number: 20180146
NCT Number: 04221542

A Phase 1 Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of AMG 509 in Subjects With mCRPC

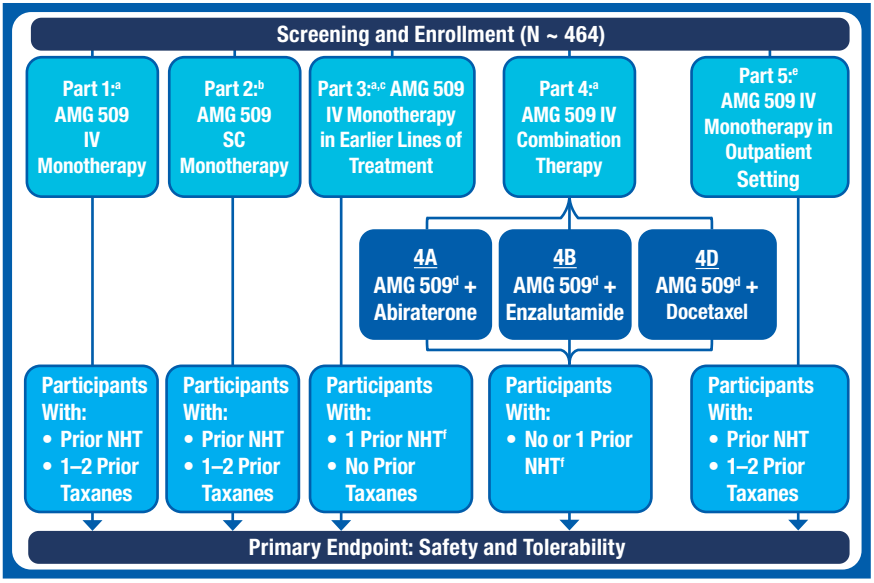
Primary Endpoints:

- Incidence of TEAEs and TRAEs; DLTs; number of participants with changes in vital signs, ECG, and clinical laboratory test results

Key Secondary Endpoints:

- OR, PSA response, PFS (radiographic and PSA), OS, DOR (radiographic and PSA), time to progression (radiographic and PSA), and PK

Study Design:



[a]Dose exploration and dose expansion.
[b]Dose exploration.
[c]Part 3 assessment is per the MTD or RP2D determined in part 1 dose exploration.
[d]The doses of AMG 509 used for 4A, 4B, and 4D were doses that were found safe and tolerable during part 1.
[e]Dosage regimen in part 5 was based on the dosage regimen explored in part 1 expansion and the recommendations of Dose Level Review Team.
[f]Given in any disease setting.

Products under investigational study have not been approved by any regulatory authority.

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Key Summary Point:

This is a phase 1 study evaluating the safety, tolerability, PK, and efficacy of AMG 509 in mCRPC subjects, including monotherapy, combination with abiraterone or enzalutamide or docetaxel, and IV or SC administration

Key Inclusion Criteria:

- Histologically or cytologically confirmed mCRPC
- Parts 1, 2, and 5: Previously treated with NHT and 1 to 2 prior taxanes
- Part 3: Previously treated with 1 NHT (given in any disease setting) and no prior taxanes
- Part 4A, 4B, and 4D: Previously treated with no or 1 prior NHT (given in any disease setting)
- Part 4A, 4B: no or 1 prior taxane
  - (4A) No prior abiraterone
  - (4B) No prior enzalutamide, apalutamide, or darolutamide
- Part 4D: No prior docetaxel

Key Exclusion Criteria:

- Any histology different from adenocarcinoma
- Radiation therapy within 4 weeks of the first dose
- Untreated CNS metastases or leptomeningeal disease
- Confirmed history or current autoimmune disease or other diseases resulting in permanent immunosuppression or requiring permanent immunosuppressive therapy
- History of arterial (within 12 months of AMG 509 initiation) or venous (within 6 months of AMG 509 initiation) thrombosis
- MI and/or symptomatic CHF within 12 months of the first dose with the exception of ischemia or non-STEMI controlled with stent placement more than 6 months prior to the first dose of AMG 509
- Any anticancer therapy or immunotherapy within 4 weeks of the start of the first dose, not including LHRH/GnRH analogs (agonist/antagonist)
- Patients on a stable bisphosphonate or denosumab regimen for ≥ 30 days before enrollment are eligible

Additional Information:

- www.clinicaltrials.gov Identifier—NCT04221542
- www.amgentrials.com Protocol Number—20180146

CHF = congestive heart failure; CNS = central nervous system; DLT = dose-limiting toxicity; DOR = duration of response; ECG = electrocardiogram; GnRH = gonadotropin-releasing hormone; IV = intravenous; LHRH = luteinizing hormone–releasing hormone; mCRPC = metastatic castration-resistant prostate cancer; MI = myocardial infarction; MTD = maximum tolerated dose; NHT = novel hormonal therapy; OR = objective response; OS = overall survival; PFS = progression-free survival; PK = pharmacokinetics; PSA = prostate-specific antigen; RP2D = recommended phase 2 dose; SC = subcutaneous; STEMI = ST-elevation myocardial infarction; TEAE = treatment-emergent adverse event; TRAE = treatment-related adverse event.

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