REGN4336 & CEMIPLIMAB
AN INVESTIGATIONAL PSMAxCD3 BISPECIFIC ANTIBODY ALONE OR IN COMBINATION WITH A PD-1 MONOCLONAL ANTIBODY

A PHASE 1/2 STUDY OF REGN4336 MONOTHERAPY OR COMBINATION THERAPY WITH CEMIPLIMAB IN PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

CLINICAL TRIAL DESIGN

Phase 1
Dose escalation
REGN4336
Multiple dose levels (SC) QW or Q3W monotherapy or combination therapy with cemiplimab (IV) Q3W

Phase 2
Dose expansion
REGN4336
RP2D (SC) QW or Q3W monotherapy or combination therapy with cemiplimab (IV) Q3W

Primary endpoints:
Safety, DLTs, REGN4336 concentrations in serum

Secondary endpoints:
ORR,a % of patients with ≥50% and ≥90% reduction in PSA from baseline, immunogenicity

Primary endpoint:
ORR

Secondary endpoints:
Safety, DLTs, % of patients with ≥50% and ≥90% reduction in PSA from baseline, immunogenicity, REGN4336 concentrations in serum

Patients With Metastatic Castration-Resistant Prostate Cancer

Estimated enrollment
N = 199

*Per modified PCWG3 criteria.

DLTs=dose-limiting toxicities; IV=intravenous; ORR=objective response rate; PCWG3=prostate cancer working group 3; PD-1=programmed cell death protein 1; PSA=prostate-specific antigen; QW=once every week; Q3W=once every 3 weeks; RP2D=recommended phase 2 dose; SC=subcutaneous.

Cemiplimab has not been fully evaluated by regulatory authorities in cancer types and dosing regimens outside of the approved labels. REGN4336 is an investigational agent and has not been approved by the US Food and Drug Administration or any other regulatory agency worldwide.

NCT05125016
https://www.clinicaltrials.gov/ct2/show/NCT05125016

UNB-EM-0027 V1.0
May 2022
Selected inclusion criteria:

- Histologically or cytologically confirmed adenocarcinoma of the prostate without pure small cell carcinoma
- mCRPC with PSA value at screening ≥4 ng/mL that has progressed within 6 months prior to screening
- Progression on or intolerance to prior treatment with ≥2 lines systemic therapy approved in the metastatic and/or castration-resistant setting, including at least 1 second-generation anti-androgen therapy in addition to ADT

Selected exclusion criteria:

- Prior treatment with an approved systemic therapy within 3 weeks of dosing or has not yet recovered (i.e., grade ≤1 or baseline) from any acute toxicities
- Previous systemic biologic therapy within 5 half-lives of first dose of study therapy
- Prior treatment with PSMA-targeting therapy
- Conditions requiring current/continuous corticosteroid therapy (>10 mg prednisone/day or anti-inflammatory equivalent) within 1 week prior to the first dose of study therapy
- Ongoing or recent (within 5 years) evidence of significant autoimmune disease that required treatment with systemic immunosuppressive treatments
- Encephalitis, meningitis, neurodegenerative disease, or uncontrolled seizures in the year prior to first dose of study therapy
- Uncontrolled infection with HIV, hepatitis B or hepatitis C infection; or diagnosis of immunodeficiency

Other protocol-defined inclusion/exclusion criteria apply.

*aIncludes neurodegenerative diseases with the exception of mild dementia that does not interfere with ADLs.

ADLs=activities of daily living; ADT=androgen deprivation therapy; HIV=human immunodeficiency virus; mCRPC=metastatic, castration-resistant prostate cancer; PSA=prostate-specific antigen; PSMA=prostate specific membrane antigen.

For more information, visit www.clinicaltrials.gov or please call 844-REGN-MID.
NCT05125016
https://www.clinicaltrials.gov/ct2/show/NCT05125016

Cemiplimab has not been fully evaluated by regulatory authorities in cancer types and dosing regimens outside of the approved labels. REGN4336 is an investigational agent and has not been approved by the US Food and Drug Administration or any other regulatory agency worldwide.