A Phase 1 Study of REGN6569 With Cemiplimab in Patients With Advanced Solid Tumor Malignancies

**Clinical Trial Design**

**Phase 1**
- **Dose escalation**
  - REGN6569 multiple dose levels (IV) monotherapy lead-in followed by combination therapy with cemiplimab (IV)
- **Primary endpoints:** Safety, DLTs
- **Secondary endpoints:** ORR, % change in GITR+ Treg density

**Phase 2**
- **Dose expansion**
  - REGN6569 RP2D (IV) monotherapy lead-in followed by combination therapy with cemiplimab (IV)
- **Primary endpoints:** ORR, % change in GITR+ Treg density
- **Secondary endpoints:** ORR, DCR, DOR, PFS, OS, safety, immunogenicity, drug concentrations of REGN6569 and cemiplimab in serum

**Patients With Advanced Solid Tumor Malignancies**
- Estimated enrollment $N = 85$

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DCR=disease control rate; DLTs=dose-limiting toxicities; DOR=duration of response; GITR=glucocorticoid-induced tumor necrosis factor-related protein; IV=intravenous; N=number of patients; ORR=objective response rate; OS=overall survival; PD-1=programmed cell death protein-1; PFS=progression-free survival; RP2D=recommended phase 2 dose; Treg=regulatory T cell.

NCT04465487
https://www.clinicaltrials.gov/ct2/show/NCT04465487

Cemiplimab has not been fully evaluated by regulatory authorities in cancer types and dosing regimens outside of the approved labels. REGN6569 is an investigational agent and has not been approved by the US Food and Drug Administration or any other regulatory agency worldwide.
A PHASE 1 STUDY OF REGN6569 WITH CEMIPLIMAB IN PATIENTS WITH ADVANCED SOLID TUMOR MALIGNANCIES

Selected inclusion criteria:

• Dose escalation cohorts: histologically or cytologically confirmed advanced stage (unresectable or metastatic) solid tumor malignancy
• Dose expansion cohorts: histologically or cytologically confirmed advanced stage (unresectable or metastatic) head and neck squamous cell carcinoma
• Able and willing to provide tumor tissue at baseline and while on treatment with at least 1 soft tissue lesion amenable to biopsy by ultrasound or CT-guided biopsy
• No prior history of immune checkpoint blockade therapy
• Exhausted all available treatment options for their disease, with no standard therapy likely to convey clinical benefit

Selected exclusion criteria:

• Prior treatment with GITR-targeted therapy
• Previous systemic biologic therapy within 5 half-lives of the first dose of study therapy
• Conditions requiring ongoing/continuous corticosteroid therapy (>10 mg prednisone/day or anti-inflammatory equivalent) within 14 days 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
• Known history of, or any evidence of, interstitial lung disease or active, non-infectious pneumonitis in the past 5 years
• Uncontrolled infection with HIV, hepatitis B or hepatitis C infection, or diagnosis of immunodeficiency
• Received a live vaccine within 4 weeks of planned start of study medication
• Dose escalation only: received a COVID-19 vaccination within 1 week of planned start of study medication or for which the planned COVID-19 vaccinations would not be completed 1 week prior to start of study
• Prior allogeneic stem cell transplantation or received organ transplants at any time, or autologous stem cell transplantation

Other protocol-defined inclusion/exclusion criteria apply.
*A history of radiation pneumonitis in the radiation field is permitted as long as pneumonitis resolved ≥6 months prior to the first dose of study therapy.


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