NCT04465487 PHASE 1

Study of investigational REGN6569 + cemiplimab in patients with **advanced solid tumors**

Primary Objective: evaluate the safety, tolerability, and antitumor activity of REGN6569 and cemiplimab in patients with advanced solid tumor malignancies

PATIENTS WITH ADVANCED SOLID TUMOR MALIGNANCIES (N≈85)

OPEN LABEL INTERVENTION

Dose Escalation

REGN6569 (IV) + cemiplimab (IV)

Dose Expansion

REGN6569 (IV) + cemiplimab (IV)

Primary Endpoints

Dose escalation: Safety and tolerability
Dose expansion: Objective response rate

Key Secondary Endpoints

- Objective response rate
- Disease control rate
- Duration of response
- Progression free survival
- Overall survival
- **Dose escalation:** Safety and tolerability

FIND OUT MORE
Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT04465487

This information is intended for investigators interested in open clinical trials.
The use of REGN6569 + cemiplimab described herein is investigational and has not been evaluated by any regulatory authority.
Please see full prescribing information in your country for cemiplimab.

IV, intravenous; N, number of patients; PD-1, programmed cell death protein-1; TNBC, triple-negative breast cancer.

REGENERON® MEDICAL AFFAIRS

NCT04465487 | PHASE 1

REGN6569

An Investigational Anti-GITR Monoclonal Antibody
Designed to bind to GITR on Treg cells, encouraging their depletion[1]

+

CEMIPLIMAB

A Fully Human PD-1 Monoclonal Antibody
Designed to block cancer cells from using the PD-1 pathway to suppress T-cell activation[2]

SELECTED INCLUSION CRITERIA[a]

- **Dose-escalation cohorts:** Advanced stage solid tumor malignancy
- Able and willing to provide tumor tissue at baseline and while on treatment, with at least 1 soft tissue lesion amenable to biopsy
- **Dose-expansion cohorts:** Advanced stage head and neck squamous cell carcinoma
- No prior history of immune checkpoint blockade therapy
- Exhausted all approved available treatment options for their disease

SELECTED EXCLUSION CRITERIA[a]

- Prior GITR-targeted therapy
- Uncontrolled HIV or hepatitis viral infections
- Prior allogeneic stem cell transplantation or received organ transplants at any time
- Evidence of ongoing or recent autoimmune disease that required systemic immunosuppressive treatment

For more information, visit www.clinicaltrials.gov or please call [+353 (0)61 533 400] OR [844 REGN-MID].
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[a]Inclusion/exclusion criteria include a summary of selected criteria. Please review the complete study design on clinicaltrials.gov for complete details.

GITR, glucocorticoid-induced TNFR-related protein; HIV, human immunodeficiency virus; PD-1, programmed cell death 1.

1. https://www.cancer.gov/publications/dictionaries/cancer-drug/def/anti-gitr-agonisticmonoclonal-antibody-regn6569 (Accessed May 2023). 2. Markham A, Duggan S. *Drugs*. 2018;78(17):1841-1846

Current per clinicaltrials.gov as of 2023.

REGN6569-EM-0002 September 2023.

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