NCT04590326 | PHASE 1/2 ENROLLING

Study of investigational REGN5668 + cemiplimab or ubamatamab in patients with **recurrent ovarian cancer**

Primary Objective: evaluate the safety, tolerability, pharmacokinetics and preliminary efficacy of REGN5668 with cemiplimab or ubamatamab in patients with recurrent ovarian cancer

PATIENTS WITH OVARIAN CANCER (N≈326)

OPEN LABEL INTERVENTION

Module 1

REGN5668 (IV) + cemiplimab (IV)
Q1W Q3W

Module 2

REGN5668 (IV) + ubamatamab (IV)
Q1W Q1W

Primary Endpoints

Dose escalation: Safety, tolerability, and pharmacokinetics
Dose expansion: Objective response rate[a]

Secondary Endpoints

Dose escalation: Objective response rate[b], efficacy, and immunogenicity
Dose expanstion: Safety, pharmacokinetics, efficacy, and immunogenicity

FIND OUT MORE

Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT04590326

This information is intended for investigators interested in open clinical trials.
The use of REGN5668 + cemiplimab or ubamatamab described herein is investigational and has not been evaluated by any regulatory authority.
Please see full prescribing information in your country for cemiplimab.

[a]Assessed using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. [b]Assessed using immune-based RECIST (iRECIST).
IV, intravenous; N, number of patients; Q1W, administered every week; Q3W, administered every three weeks.

REGENERON®
MEDICAL AFFAIRS

NCT04590326

PHASE 1/2 ENROLLING

REGN5668

An Investigational MUC16xCD28 Bispecific Antibody
Designed to bridge MUC16 on cancer cells with CD28 on T-cells[1]

+

UBAMATAMAB

An Investigational MUC16xCD3 Bispecific Antibody
Designed to bridge MUC16 on cancer cells with CD3 on T cells[2]

OR

+

CEMIPLIMAB

An Investigational, Fully Human PD-1 Monoclonal Antibody
Designed to block cancer cells from using the PD-1 pathway to suppress T-cell activation[3]

SELECTED INCLUSION CRITERIA[a]

- 0 or 1 — ECOG PS 0 or 1
- Adequate organ and bone marrow function
- Confirmed diagnosis of advanced epithelial ovarian cancer, primary peritoneal, or fallopian tube cancer that has received at least 1 line of platinum-based systemic therapy
- Life expectancy of at least 3 months
- Serum CA-125 level ≥2x ULN

SELECTED EXCLUSION CRITERIA[a]

- Prior anti-cancer immunotherapy
- Any condition that requires ongoing/continuous corticosteroid therapy
- Recent treatment with PD-1/PDL-1 therapy or MUC16-targeted therapy
- Ongoing or recent (within 5 years) evidence of significant autoimmune disease that required treatment with systemic immunosuppressive treatments
- Has had another malignancy within the last 5 years that is progressing, requires active treatment, or has a high likelihood of recurrence
- Untreated or active primary brain tumor, CNS metastases, leptomeningeal disease, or spinal cord compression

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.

CA, cancer antigen; CD, cluster of differentiation; CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; MUC16, mucin 16; PD-1, programmed cell death 1; ULN, upper limit of normal.

Current per clinicaltrials.gov as of October 4, 2023.

1. National Cancer Institute Drug Dictionary: REGN5668. Available at: https://www.cancer.gov/publications/dictionaries/cancer-drug/def/anti-muc16-cd28-bispecific-antibody-regn5668 (Accessed May 2023).
2. Winer et al, *J Clin Oncol*, 2021;39:TPS5602. 3. Markham A, Duggan S. *Drugs*. 2018;78(17):1841-1846. TPS5602.

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