NCT03564340 | PHASE 1/2 ENROLLING

Study of investigational ubamatamab ± cemiplimab in patients with **recurrent ovarian cancer**

Primary Objective: evaluate the safety, pharmacokinetics, and determine a recommended phase 2 dose of ubamatamab ± cemiplimab in patients with recurrent ovarian cancer

PATIENTS WITH OVARIAN CANCER (N≈554)

OPEN LABEL INTERVENTION

Ubamatamab[a] (IV or SC)

Ubamatamab[a] (IV or SC) + cemiplimab[b] (IV)

Primary Endpoints

Dose escalation: Safety, pharmacokinetics
Dose expansion: Objective response rate[c]
Recommended phase 2 dose

Secondary Endpoints

Dose escalation: Objective response rate[c]
Dose expansion: Safety, pharmacokinetics, patient-reported outcomes
Efficacy
Immunogenicity

FIND OUT MORE

Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT03564340

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

[a]Dose expansion + escalation. [b]Administered after an ubamatamab monotherapy dose has been selected. [c]Assessed using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 and immune-based RECIST (iRECIST).
IV, intravenous; N, number of patients; SC, subcutaneous.

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PHASE 1/2 ENROLLING

UBAMATAMAB

An Investigational MUC16xCD3 Bispecific Antibody

Designed to bridge MUC16 on cancer cells with CD3 on T cells[1]

+

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[2]

SELECTED INCLUSION CRITERIA[a]

- Confirmed diagnosis of advanced epithelial ovarian cancer, primary peritoneal, or fallopian tube cancer
- Adequate organ and bone marrow function
- Serum CA-125 level ≥2x ULN
- Life expectancy of at least 3 months
- Received at least 1 line of platinum-containing therapy or platinum-intolerant
- Phase 2 expansion cohorts only: Received 1 to 4 lines of platinum-based therapy prior treatment with PARP inhibitor or bevacizumab

SELECTED EXCLUSION CRITERIA[a]

- Recent treatment with PD-1/PD-L1 therapy
- Untreated or active primary brain tumor, CNS metastases, or spinal cord compression
- Expansion cohort only: More than 4 prior lines of cytotoxic chemotherapy
- Either historical or current cardiac findings
- Prior treatment with a MUC16-targeted therapy
- Severe and/or uncontrolled hypertension

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; PARP, poly ADP-ribose polymerase; PD-1/PD-L1, programmed cell death protein/ligand 1; ULN, upper limit of normal.

Current per clinicaltrials.gov as of December 19, 2023.

1. Winer et al, *J Clin Oncol*, 2021;39:TPS5602. 2. Markham A, Duggan S. *Drugs*. 2018;78(17):1841-1846
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