

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.

^aDose expansion + escalation. ^bAdministered after an ubamatamab monotherapy dose has been selected. ^cAssessed 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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UBAMATAMAB

An Investigational MUC16xCD3 Bispecific Antibody

Designed to bridge MUC16 on cancer cells with CD3 on T cells¹



CEMIPLIMAB

An Investigational, Fully Human PD-1 Monoclonal Antibody

Designed to block cancer cells from using the PD-1 pathway to suppress T-cell activation²

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 $\geq 2 \times$ 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.

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^aInclusion/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 September 8, 2023.

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

REGN4018-EM-0002 October 2023.

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