NCT04916002 | PHASE 2 ENROLLING

Study of investigational vidutolimod + cemiplimab in patients with **advanced cancers**

Primary Objective: evaluate the safety, tolerability, and efficacy of vidutolimod + cemiplimab in adult patients with advanced or metastatic CSCC, MCC, TNBC, BCC, and NSCLC

PATIENTS WITH ADVANCED CANCERS (N≈200)

OPEN LABEL INTERVENTION

VIDUTOLIMOD (IT)[a] + CEMIPLIMAB (IV)

Arm A1	Arm A2	Arm B1	Arm B2	Arm C1	Arm C2	Arm D	Arm E
CSCC: Patients who have not received prior systemic therapy	**CSCC:** Patients who have progressed on PD-1 therapy or discontinued treatment within 3 months	**MCC:** Patients who have not received prior systemic therapy	**MCC:** Patients who have progressed on PD-1 therapy or discontinued treatment within 3 months	**TNBC:** Patients who have not received prior therapy with immune checkpoint inhibitors	**TNBC:** Patients who have progressed on PD-1 therapy or discontinued treatment within 3 months	**BCC:** Patients who have not received prior therapy[b]	**NSCLC[c]:** Patients whose tumors have high PD-L1 expression (TPS ≥ 50%) and have not received prior anti-PD-1/PD-L1 therapy
Q3W	**Q3W**	**Q3W**	**Q3W**	**Q3W**	**Q3W**	**Q3W**	**Q3W**

Primary Endpoint

Objective response rate[d]

Secondary Endpoints

Safety and tolerability

Efficacy[d]

FIND OUT MORE

Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT04916002

This information is intended for investigators interested in open clinical trials

The use of vidutolimod + 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]The first dose of vidutolimod may be administered subcutaneously (SC) or IT at the discretion of Investigator. [b]With neither hedgehog pathway inhibitors nor immune checkpoint inhibitors [c]Participants with advanced NSCLC (metastatic or locally advanced who are not candidates for definitive chemoradiation, nor candidates for surgical resection) and are amenable to IT therapy for advanced NSCLC; patients with EGFR, ALK, or ROS1 aberrations, are not eligible. [d]Assessed using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.

ALK, anaplastic lymphoma kinase; BCC, basal cell carcinoma; CSCC, cutaneous squamous cell carcinaoma; EGFR, epidermal growth factor receptor; IT, intratumoral; IV, intravenous; MCC, Merkel cell carcinoma; N, number of patients; NSCLC, non-small cell lung cancer; PD-1, programmed cell death protein-1; PD-L1, programmed cell death ligand-1; Q3W, administered every three weeks TNBC, triple-negative breast cancer; TPS, tumor prognostic score.

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VIDUTOLIMOD

An Investigational TLR9 Agonist

Designed to activate TLR9, a receptor that detects intracellular pathogens, to trigger pDC secretion of the cytokine IFN-α and T-cell responses against tumors[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]

- Histopathologically confirmed diagnosis of cancer that is metastatic or unresectable at screening
- Measurable disease, as defined by RECIST v1.1
- Able to provide tissue from a core or excisional/ incisional biopsy
- Adequate organ function
- 0 or 1 — ECOG PS 0 or 1

For more information, visit www.clinicaltrials.gov or please call 844 REGN-MID.
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https://clinicaltrials.gov/ct2/show/NCT04916002

SELECTED EXCLUSION CRITERIA[a]

- Received radiation therapy within 2 weeks before first dose of study treatment
- History of immune-mediated AE leading to permanent discontinuation due to prior PD-1-blocking antibody
- Received systemic pharmacologic doses of corticosteroids >10 mg/day prednisone within 30 days before first dose of study treatment
- Severe uncontrolled cardiac disease within 12 months of screening[b]
- Known additional malignancy that is progressing or required active treatment within the past 3 years[c]
- Untreated, symptomatic, or enlarging central nervous system metastases or carcinomatous meningitis
- Known history of immunodeficiency

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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. [b]Including but not limited to poorly controlled hypertension, unstable angina, myocardial infarction, congestive heart failure (New York Heart Association Class II or greater), pericarditis within the previous 6 months, cerebrovascular accident, or implanted or continuous use of a pacemaker or defibrillator. [c]Exceptions include cancers that have undergone potentially curative therapy, e.g., basal cell carcinoma of the skin, squamous cell carcinoma of the skin, localized prostate cancer with prostate-specific antigen level below 4.0 ng/mL, in situ cervical cancer on biopsy or a squamous intraepithelial lesion on Papanicolaou smear, and thyroid cancer (except anaplastic), in situ breast cancer, and adjuvant hormonal therapy for breast cancer >3 years from curative-intent surgical resection.

AE, adverse event; ECOG PS, Eastern Cooperative Oncology Group performance status; IFN-α, interferon α; PD-1, programmed cell death protein-1; pDC, plasmacytoid dendritic cells; RECIST, Response Evaluation Criteria In Solid Tumors; TLR9, toll-like receptor 9.

Current per clinicaltrials.gov as of August 14, 2023.

1. Sabree SA et al. *J Immunother Cancer.* 2021;9(6):e002484. 2. Markham A, Duggan S. *Drugs.* 2018;78(17):1841-1846.
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