NCT04916002

PHASE 2 ENROLLING

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

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

PATIENTS WITH ADVANCED OR METASTATIC CANCERS (N≈225)

OPEN LABEL INTERVENTION

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

All arms Q3W

Arm A1
CSCC: Patients who have not received prior systemic therapy

Arm A2
CSCC: Patients who have progressed while receiving a PD-1–blocking antibody or within 12 weeks of discontinuation of the PD-1 blocking antibody

Arm B1
MCC: Patients who have not received prior systemic therapy

Arm B2
MCC: Patients who have progressed while receiving a PD-1–blocking antibody or within 12 weeks of discontinuation of the PD-1 blocking antibody

Arm C1
TNBC: Patients who have not received prior therapy with immune checkpoint inhibitors and who have received prior treatment with SG, T-DXd (HER2-low disease) and PARPi (*BRCA*m TNBC)

Arm C2
TNBC: Patients who have progressed while receiving a PD-1–blocking antibody or within 12 weeks of discontinuation of the PD-1 blocking antibody and who have received prior treatment with SG, T-DXd (HER2-low disease) and PARPi (*BRCA*m TNBC)

Arm D
BCC[b]: Patients who have not received prior therapy

Arm E
NSCLC[c]: Patients whose tumors have high PD-L1 expression (TPS ≥ 50%) and have not received prior anti-PD-1/PD-L1 therapy[d]

Arm F
OPSCC: Patients whose tumors have PD-L1 CPS ≥ 1 and have not received prior systemic therapy

Primary Endpoint

Objective response rate[e]

Secondary Endpoints

Safety and tolerability

Efficacy[e]

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]With no EGFR, ALK, or ROS1 aberrations. [e]Assessed using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.

ALK, anaplastic lymphoma kinase; BCC, basal cell carcinoma; *BRCA*, BReast CAncer gene; CPS, combined positive score; CSCC, cutaneous squamous cell carcinoma; EGFR, epidermal growth factor receptor; HER2, human epidermal growth factor receptor 2; IT, intratumoral; IV, intravenous; MCC, Merkel cell carcinoma; N, number of patients; NSCLC, non-small cell lung cancer; OPSCC, oropharynx squamous cell carcinoma; PARPi, poly-ADP ribose polymerase; PD-1, programmed cell death protein-1; PD-L1, programmed cell death ligand-1; Q3W, administered every three weeks; SG, sacituzumab govitecan; T-DXd, trastuzumab deruxtecan; TNBC, triple-negative breast cancer; TPS, tumor prognostic score.

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MEDICAL AFFAIRS

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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
- Adequate organ function
- 0 or 1 — ECOG PS 0 or 1

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 15 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

For more information, visit www.clinicaltrials.gov or please call Medical Information at 844-REGN-MID (US and Canada); +353 (0)61 533 400 (Rest of the world). NCT04916002 https://clinicaltrials.gov/ct2/show/NCT04916002

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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 February 19, 2024.

1. Sabree SA et al. *J Immunother Cancer.* 2021;9(6):e002484. 2. Markham A, Duggan S. *Drugs*. 2018;78(17):1841-1846.
Regeneron Pharmaceuticals, Inc.
Vidutolimod-EM-0001 v2.0 February 2024.

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