NCT03916627

PHASE 2 ENROLLING

Study of investigational **neoadjuvant** cemiplimab in patients with resectable **non-small cell lung cancer, hepatocellular carcinoma, and head and neck squamous cell carcinoma**

Primary Objective: evaluate the clinical activity of neoadjuvant cemiplimab in patients with resectable NSCLC, HCC, and HNSCC

PATIENTS WITH NSCLC, HCC, AND HNSCC (N≈73)

OPEN LABEL INTERVENTION

Cohort A1	Cohort A2	Cohort A3	Cohort B	Cohort B2	Cohort B3	Cohort C
NSCLC: Neoadjuvant cemiplimab (IV); adjuvant cemiplimab (IV) + platinum doublet (IV)	**NSCLC:** Neoadjuvant and adjuvant cemiplimab (IV) + platinum doublet (IV)	**NSCLC:** Neoadjuvant platinum doublet (IV); adjuvant cemiplimab (IV) + platinum doublet (IV)	**HCC:** Neoadjuvant and adjuvant cemiplimab (IV)	**HCC:** Neoadjuvant SBRT 8 Gy x 3 fractions followed by cemiplimab (IV); adjuvant cemiplimab (IV)	**HCC:** Neoadjuvant and adjuvant cemiplimab (IV) + fianlimab (IV)	**HNSCC:** Neoadjuvant cemiplimab (IV); adjuvant SOC radiation ± chemotherapy + cemiplimab (IV)
No longer enrolling	No longer enrolling	No longer enrolling				No longer enrolling

Primary Endpoints

Major pathologic response[a] | Significant tumor necrosis[b] | Major treatment effect[c]

Secondary Endpoints

- Delay to surgery
- Event-free survival
- Disease-free survival
- Overall response rate[d]
- Overall survival
- Safety and tolerability
- Change in CD8 T-cell density

FIND OUT MORE

Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT03916627

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

[a]Cohorts A1, A2, A3. [b]Cohorts B, B2, B3. [c]Cohort C. [d]Assessed using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 based on investigator assessment.
HCC, hepatocellular carcinoma; HNSCC, head and neck squamous cell carcinoma; IV, intravenous; N, number of patients; NSCLC, non-small cell lung cancer; SBRT, stereotactic body radiotherapy; SOC, standard of care.

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NCT03916627 | PHASE 2 ENROLLING

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[1]

+

FIANLIMAB

An Investigational LAG-3 Monoclonal Antibody[2]
Designed to bind to LAG-3 on T cells to block the LAG-3 inhibitory signal[3]

SELECTED INCLUSION CRITERIA[a]

- Known diagnosis of NSCLC, HCC, or HNSCC
- Willing and able to provide blood samples at the indicated time points
- Willing and able to have excisional or core needle biopsies of tumor
- 0 or 1 — ECOG PS 0 or 1
- Patient is determined to be a surgical candidate for resection of their tumor
- Adequate organ and bone marrow function

SELECTED EXCLUSION CRITERIA[a]

- Any systemic anti-cancer therapy or radiotherapy within 6 months
- Tumor burden, or pace of tumor growth, in the opinion of the Investigator, will not permit delaying surgery
- Participation in a study of an investigational agent or an investigational device within 4 weeks of study therapy or 5 half-lives
- Known, additional malignancy that is progressing and/or requires active treatment[b]
- History of interstitial lung disease or active, noninfectious pneumonitis that required immune-suppressive doses of glucocorticoids[c]
- NSCLC cohorts only: Patients do not have a history of smoking[d]
- NSCLC cohorts only: Patients with tumors tested positive for EGFR gene mutations, ALK gene translocations, or ROS1 fusions

For more information, visit www.clinicaltrials.gov or please call 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. [b]Exceptions include patients with: basal cell carcinoma of the skin or squamous cell carcinoma of the skin that has undergone potentially curative therapy; in situ cervical or anal cancer; prostate cancer on a stable dose of hormonal therapy without rising PSA; breast cancer who have been treated with curative intent, who may be on hormonal therapy. [c]A history of radiation pneumonitis in the radiation field is permitted as long as pneumonitis resolved ≥6 months prior to study treatment. [d]History of smoking is defined as smoking ≥100 cigarettes in a lifetime.

ALK, anaplastic lymphoma kinase; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; HCC, hepatocellular carcinoma; HNSCC, head and neck squamous cell carcinoma; LAG-3, lymphocyte activation gene 3; NSCLC, non-small cell lung cancer; PD-1, programmed cell death protein-1; ROS1, c-ros oncogene 1.

1. Markham A, Duggan S. *Drugs.* 2018;78(17):1841-1846. 2. Hamid O, et al. *J Clin Oncol.* 2021;39(Suppl. 15);abstr 9515. 3. Goldberg MV, Drake CG. Curr Top Microbiol Immunol. 2011;344:269–278.

Current per clinicaltrials.gov as of May 31, 2023.

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