NCT05785767 | PHASE 2/3 ENROLLING

Study of investigational fianlimab + cemiplimab in patients with **advanced non-small cell lung cancer**

Primary Objective: compare safety and efficacy of fianlimab + cemiplimab to cemiplimab alone in patients with previously untreated, unresectable advanced NSCLC with PD-L1 TPS ≥ 50%

PATIENTS WITH ADVANCED NSCLC (N≈850)

INTERVENTION

Phase 2 (R 1:1:1)

- **Arm A**: High-dose Fianlimab (IV) + Cemiplimab (IV) Q3W
- **Arm B**: Low-dose Fianlimab (IV) + Cemiplimab (IV) Q3W
- **Arm C**: Cemiplimab (IV) + Placebo (IV) Q3W

Phase 3 (R 1:1)

- **Arm A or B dose**: Fianlimab (IV) + Cemiplimab (IV) Q3W
- **Arm C**: Cemiplimab (IV) + Placebo (IV) Q3W

Primary Endpoints

Phase 2/3: Objective response rate[a] **Phase 3:** Overall survival

Secondary Endpoints

Phase 2: Overall survival
Safety and tolerability
Disease control rate
Time to response
Duration of response
Progression-free survival
Immunogenicity
Quality of life
Pharmacokinetics

FIND OUT MORE

Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT05785767

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]Assessed using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.
NSCLC, non-small cell lung cancer; IV, intravenous; N, number of patients; PD-L1, programmed cell death ligand-1; Q3W, administered every three weeks; R, randomized; TPS, tumor proportion score.

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FIANLIMAB

An Investigational LAG-3 Monoclonal Antibody[1]
Designed to bind to LAG-3 on T cells to block the LAG-3 inhibitory signal[2]

+

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[3]

SELECTED INCLUSION CRITERIA[a]

- PD-L1 — Expression of PD-L1 in ≥50% tumor cells
- Stage IIIB or IIIC NSCLC patients who are not candidates for surgical resection or chemoradiation or patients with metastatic disease with no prior systemic treatment
- Radiographically measurable lesion by CT or MRI per RECIST v1.1
- Adequate organ and bone marrow function
- 0 or 1 — ECOG PS 0 or 1

SELECTED EXCLUSION CRITERIA[a]

- Never smoked[b]
- Ongoing or recent (within 2 years) evidence of an autoimmune disease that required systemic treatment with immunosuppressive agents[c]
- Tumors expressing EGFR mutations, ALK rearrangement, or ROS1 fusions
- Treatment with prior systemic therapies[d]
- Active or untreated brain metastases or spinal cord compression[e]
- Encephalitis, meningitis, or uncontrolled seizures in the year prior to enrollment

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]Defined as ≤ 100 cigarettes in a lifetime [c]The following are not exclusionary: vitiligo, childhood asthma that has resolved, residual hypothyroidism that required only hormone replacement, or psoriasis that does not require systemic treatment. [d]Patients who have received prior systemic therapies are excluded with the exception of the following: adjuvant or neoadjuvant platinum-based doublet chemotherapy if recurrent or metastatic disease develops more than 6 months after completing therapy, anti-PD-L1 with or without LAG-3 as an adjuvant or neoadjuvant therapy if completed > 12 months prior to enrollment, and/or prior exposure to other immunomodulatory or vaccine therapies such as anti-CTLA-4 antibodies if completed > 3 months prior to enrollment. [e]Patients are eligible if central nervous system (CNS) metastases are adequately treated and patients have neurologically returned to baseline (except for residual signs or symptoms related to the CNS treatment) for at least 2 weeks prior to enrollment. Patients must be off (immunosuppressive doses of) corticosteroid therapy.

ALK, anaplastic lymphoma kinase; CT, computerized tomography; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; LAG-3, lymphocyte activation gene-3; MRI, magnetic resonance imaging; NSCLC, non-small cell lung cancer; PD-1/PD-L1, programmed cell death protein/ligand 1; RECIST, Response Evaluation Criteria in Solid Tumors; ROS1, ROS proto-oncogene 1.

Current per clinicaltrials.gov as of September 15, 2023.

1. Hamid O, et al. *J Clin Oncol*. 2021;39(Suppl. 15);abstr 9515. 2. Goldberg MV, Drake CG. *Curr Top Microbiol Immunol*. 2011;344:269–278. 3. Markham A, Duggan S. *Drugs*. 2018;78(17):1841-1846.
FIA-EM-0010 October 2023.

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