NCT05800015 | PHASE 2/3 ENROLLING

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

Primary Objective: evaluate the efficacy of fianlimab with cemiplimab and chemotherapy in patients with previously untreated, unresectable, advanced NSCLC regardless of PD-L1 expression

**PATIENTS WITH ADVANCED NSCLC (N≈950)**

**INTERVENTION**

## Phase 2 (R 1:1:1)

### Arm A
**High-dose fianlimab (IV) + cemiplimab (IV) + chemotherapy (IV) Q3W**

### Arm B
**Low-dose fianlimab (IV) + cemiplimab (IV) + chemotherapy (IV) Q3W**

### Arm C
**Cemiplimab (IV) + placebo (IV) + chemotherapy (IV) Q3W**

## Phase 3 (R 1:1)

### Arm A or B dose
**Fianlimab (IV) + cemiplimab (IV) + chemotherapy (IV) Q3W**

### Arm C
**Cemiplimab (IV) + placebo (IV) + chemotherapy (IV) Q3W**

## Primary Endpoints

**Phase 2:** Objective response rate[a,b]

**Phase 3:** Overall survival

## Secondary Endpoints

**Phase 2:** Overall survival
Safety and tolerability
Overall response rate[c]
Disease control rate[b,c]
Time to tumor response[b,c]
Duration of response[b,c]
Progression-free survival[b,c]
Immunogenicity
**Phase 2 and 3:** Pharmakokinetics
**Phase 2 and 3:** Quality of Life

**FIND OUT MORE**

Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT05800015

**This information is intended for investigators interested in open clinical trials.**
**The use of fianlimab + 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]Assessed using Response Evaluation Criteria in Solid Tumors (RECIST). [b]Based on on Blinded Independent Central Review (BICR).
[c]Based on investigator assessment.
IV, intravenous; N, number of patients; ; NSCLC, non small-cell lung cancer; Q3W, administered every three weeks; R, randomized.

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**NCT05800015** **PHASE 2/3 ENROLLING**

# 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]

- 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
- A valid result of PD-L1, regardless of expression level using an assay performed by a local laboratory (with confirmation by a central laboratory) or a central laboratory
- Radiographically measurable lesion by CT or MRI per RECIST v1.1
- 0 or 1 — ECPG PS 0 or 1
- Adequate organ and bone marrow function

## SELECTED EXCLUSION CRITERIA[a]

- Active or untreated brain metastases, or spinal cord compression[b]
- Tumors expressing EGFR mutations, ALK rearrangement, or ROS1 fusions
- Ongoing or recent evidence (within 2 years) of an autoimmune disease that required systemic treatment with immunosuppressive agents
- Treatment with prior systemic therapies[c]
- Encephalitis, meningitis, or uncontrolled seizures in the year prior to enrollment.
- History of interstitial lung disease
- Known primary immunodeficiencies either cellular or combined T- and B-cell immunodeficiencies

**For more information, visit www.clinicaltrials.gov or please call [+353 (0)61 533 400 or 844 REGN-MID]. NCT05800015**
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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]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.
[c]Patients who have received prior systemic therapies are excluded with the exception of the following:

- Adjuvant or neoadjuvant platinum-based doublet chemotherapy (after surgery and/or radiation therapy) if recurrent or metastatic disease develops more than 6 months after completing therapy as long as toxicities have resolved to CTCAE grade ≤1 or baseline with the exception of alopecia and peripheral neuropathy.
- Anti-PD-(L)1 with or without LAG-3 as an adjuvant or neoadjuvant therapy as long as the last dose is >12 months prior to enrollment.
- Prior exposure to other immunomodulatory or vaccine therapies as an adjuvant or neoadjuvant therapy such as anti-CTLA-4 antibodies as long as the last dose is >6 months prior to enrollment.

**Note:** Immune-mediated AEs must be resolved to CTCAE grade ≤1 or baseline by the time of enrollment. Endocrine immune-mediated AEs controlled with hormonal or other non-immunosuppressive therapies without resolution prior to enrollment are allowed.

AE, adverse event; ALK, anaplastic lymphoma kinase; CT, computerized tomography; CTCAE, Common Terminology Criteria for Adverse Events; 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 December 20, 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.
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