

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

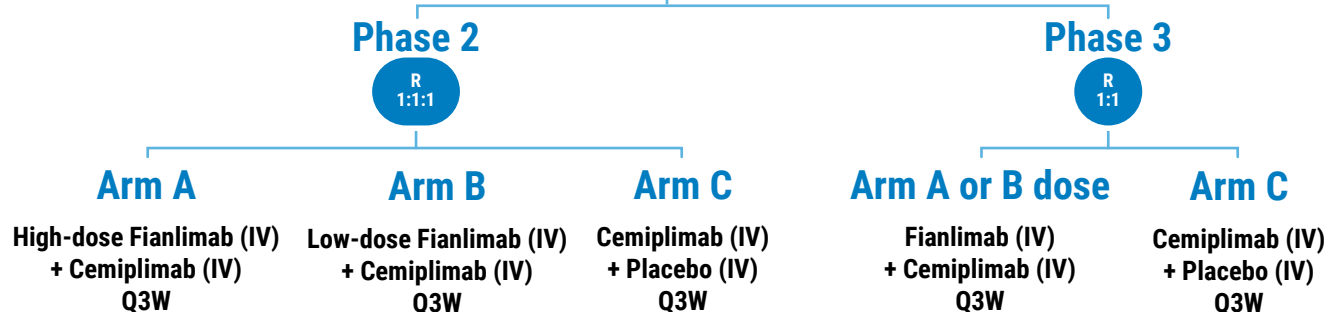


Primary Objective: compare safety and efficacy of fianlimab + cemiplimab to cemiplimab alone in patients with previously untreated, unresectable advanced NSCLC with PD-L1 TPS \geq 50%



PATIENTS WITH ADVANCED NSCLC (N \approx 850)

INTERVENTION



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.

^aAssessed 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.

NCT05785767

PHASE 2/3 ENROLLING

FIANLIMAB

An Investigational LAG-3 Monoclonal Antibody¹

Designed to bind to LAG-3 on T cells to block the LAG-3 inhibitory signal²



CEMIPLIMAB

An Investigational, Fully Human PD-1 Monoclonal Antibody

Designed to block cancer cells from using the PD-1 pathway to suppress T-cell activation³

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



ECOG PS 0 or 1



For more information, visit www.clinicaltrials.gov or please call +353 (0)61 533 400.
NCT05785767
<https://clinicaltrials.gov/ct2/show/NCT05785767>

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

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^aInclusion/exclusion criteria include a summary of selected criteria. Please review the complete study design on clinicaltrials.gov for complete details. ^bDefined as ≤ 100 cigarettes in a lifetime. ^cThe 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. ^dPatients 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. ^ePatients 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.

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