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
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 as performed by 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].
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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:

- Prior platinum-based doublet chemotherapy if recurrent or metastatic disease develops >6 months after completing therapy and toxicities (excluding alopecia and peripheral neuropathy) resolved to CTCAE grade ≤1 or baseline;
- (Neo)adjuvant anti-PD(L)1 +/- LAG-3 if the last dose is >12 months prior to enrollment;
- Exposure to other immunomodulatory or vaccine therapies if the last dose is >3 months prior to enrollment, immune-mediated AEs have resolved to CTCAE grade ≤1 or baseline by the time of enrollment, and endocrine immune-mediated AEs are controlled.

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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