NCT03005782 | PHASE 1

Study of fianlimab with or without cemiplimab in patients with **advanced malignancies**

Evaluate the safety, tolerability, activity, and pharmacokinetics of fianlimab alone or in combination with cemiplimab for patients with advanced malignancies

PATIENTS WITH ADVANCED MALIGNANCIES (N=333)

INTERVENTION

Monotherapy: Fianlimab

Combination therapy: Fianlimab + cemiplimab

Primary Endpoints[a]

Safety and tolerability
Pharmacokinetics
Objective response rate

Secondary Endpoints[a]

Objective response rate
Best overall response
Disease control rate
Progression-free survival
Duration of response
Safety

FIND OUT MORE
Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT03005782

Fianlimab is an investigational agent and has not been approved by the US Food & Drug Administration or any other regulatory agency worldwide.
[a]Based on Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 and Lugano criteria.
N, number of patients.

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FIANLIMAB

An Investigational LAG-3 Monoclonal Antibody[1]
Binds to LAG-3 on T cells, blocking the LAG-3 inhibitory signal.
This may rescue T-cell activation and tumor response[2]

CEMIPLIMAB

An Investigational PD-1 Monoclonal Antibody
Designed to block cancer cells from using the PD-1 pathway to suppress T-cell activation[1]

NCT03005782: SELECTED INCLUSION CRITERIA

- ECOG PS ≤1
- **Dose escalation cohorts:** Patients with histologically or cytologically confirmed diagnosis of malignancy (including lymphoma) with demonstrated progression of a tumor for whom there is no available therapy[a]
- **Dose expansion cohorts:** Patients with histologically or cytologically confirmed diagnosis of a specified tumor with measurable disease. Some patients may have been previously treated with a PD-1 or PD-L1 inhibitor
- Adequate organ and bone marrow function

NCT03005782: SELECTED EXCLUSION CRITERIA

- Radiation therapy within 2 weeks prior to randomization and not recovered to baseline from any AE due to radiation
- Untreated or active central nervous system metastases
- Corticosteroid therapy (>10 mg prednisone/day or equivalent) within 1 week prior to the first dose of study drug
- Myocardial infarction within 6 months
- Prior treatment with any LAG-3 targeting biologic or small molecule
- Ongoing or recent (within 5 years) evidence of significant autoimmune disease

For more information, visit www.clinicaltrials.gov or please call 844-REGN-MID.
NCT03005782
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[a]These patients have not been previously treated with a PD-1/PD-L1 inhibitor. These patients do not require measurable disease.
AE, adverse event; CD, cluster of differentiation; ECOG PS, Eastern Cooperative Oncology Group performance status; LAG-3, lymphocyte activation gene-3; PD-1/PD-L1, programmed cell death protein/ligand 1.

Current per clinicaltrials.gov as of July 19, 2023.

1. Hamid O, et al. *J Clin Oncol.* 2021;39(Suppl. 15);abstr 9515. 2. Goldberg MV, Drake CG, et al. *Curr Top Microbiol Immunol.* 2011;344:269–278.
3. LIBTAYO® (cemiplimab-rwlc) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc.
FIA-EM-0008 August 2023.

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