NCT05352672 | PHASE 2/3 (PHASE 3 ENROLLING)

Study of fianlimab in combination with cemiplimab in adolescent and adult patients with **previously untreated unresectable locally advanced or metastic melanoma**

Primary Objective: evaluate the efficacy, safety, and antitumor activity of fianlimab + cemiplimab in patients with previously untreated unresectable locally advanced or metastatic melanoma

PATIENTS WITH ADVANCED OR METASTATIC MELANOMA (N≈1925)

INTERVENTION

R 2:2:2:1

Arm A	Arm A1	Arm B	Arm C
Fianlimab (dose 1; IV) cemiplimab (IV) Q3W	Fianlimab (dose 2; IV) cemiplimab (IV) Q3W	Pembrolizumab (IV) + placebo (IV) Q3W	Cemiplimab (IV) + placebo (IV) Q3W

Primary Endpoint

Objective response rate and Progression-free survival (Phase 2)[a]
Progression-free survival (Phase 3)[a]

Selected Secondary Endpoints

- Overall survival
- Objective response rate[a,b]
- Disease control rate[a,b]
- Duration of response[a,b]
- Progression-free survival[a,b]
- Safety and tolerability
- Pharmacokinetics
- Immunogenicity
- GHS/QoL

FIND OUT MORE

Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT05352672

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 based on Blinded Independent Central Review (BICR)
[b]or based on investigator assessment according to RECIST v1.1 and immune RECIST (iRECIST).
GHS, global health score; IV, intravenous; N, number of patients; Q3W, administered every three weeks; QoL, quality of life; R, randomization.

REGENERON® MEDICAL AFFAIRS

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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]

- ≥12 — Patients ≥12 years of age
- Histologically confirmed unresectable Stage III or Stage IV melanoma who have not received prior systemic therapy for advanced unresectable disease[b]
- Measurable disease per RECIST v1.1[c]
- 0 or 1 — **Adult patients:** ECOG PS 0 or 1; **Pediatric patients:** Karnofsky PS ≥70 (patients ≥16 years) or Lansky PS ≥70 (patients ≤16 years)
- Anticipated life expectancy ≥3 months

SELECTED EXCLUSION CRITERIA[a]

- Uveal melanoma
- Systemic immune suppression: use of immunosuppressive doses of corticosteroids (≤10mg of prednisone per day or equivalent) within 14 days of the first dose of study medication[d]
- Active or untreated brain metastases or spinal cord compression. Patients with leptomeningeal disease are excluded[e]
- Ongoing or recent (within 2 years) evidence of an autoimmune disease that required systemic treatment with immunosuppressive agents[f]
- Unknown BRAF V600 mutation status
- Treatment with other anti-cancer therapy including immunotherapy, chemotherapy, major surgery or biological therapy within 21 days prior to the first dose of trial treatment[g]

For more information, visit www.clinicaltrials.gov or please call Medical Information [844-REGN-MID (US and Canada) or +353 (0)61 533 400 (Rest of the world)]. NCT05352672 https://clinicaltrials.gov/ct2/show/NCT05352672

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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 who received adjuvant and/or neoadjuvant systemic therapies are eligible if they did not have evidence of progression or recurrence of disease and/or discontinued due to occurrence of unmanageable irAEs ≥ grade 3 (with the exclusion of endocrinopathies that are fully controlled by hormone replacement) while on such therapies. Also, patients must have had a treatment-free and disease-free interval of >6 months. Patients with acral and mucosal melanomas are eligible. Accrual will be limited to 10% of the total population. [c]Previously irradiated lesions can only be counted as target lesions if they have been demonstrated to progress and no other target lesion is available. Cutaneous lesions should be evaluated as non-target lesions. [d]Physiologic replacement doses are allowed up to and including 10 mg of prednisone per day or equivalent. Inhaled or topical steroids are permitted, if they are not for treatment of an autoimmune disorder. [e]Patients with known brain metastases are eligible if they: received radiotherapy or another appropriate standard therapy for the brain metastases, have neurologically returned to baseline (except for residual signs and symptoms related to the CNS treatment) for at least 14 days prior to enrollment, did not require immunosuppressive doses of corticosteroid therapy (>10 mg of prednisone per day or equivalent) in the 14 days prior to enrollment, are asymptomatic with a single untreated brain metastasis <10 mm in size. [f]The following are non-exclusionary: vitiligo, childhood asthma that has resolved, residual hypothyroidism that requires only hormone replacement, psoriasis not requiring systemic treatment. [g]Adjuvant hormonotherapy used for breast cancer or other hormone-sensitive cancers in long term remission is allowed.

BRAF, v-raf murine sarcoma viral oncogene homolog B1; CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; HIV, human immunodeficiency virus; irAE, immune-related adverse events; LAG-3, lymphocyte activation gene-3; PD-1, programmed cell death ligand-1; RECIST, Response Evaluation Criteria in Solid Tumors.

Current per clinicaltrials.gov as of February 14, 2024.

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-0003 v2.0 February 2024.

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