NCT05608291

PHASE 3 ENROLLING

Study Director approval email can be found in attachments

Defer to medical on accuracy

# Study of investigational **adjuvant** fianlimab + cemiplimab in patients with completely resected **high-risk melanoma**

Primary Objective: evaluate the efficacy and safety of adjuvant fianlimab + cemiplimab compared to pembrolizumab in patients with completely resected, histologically confirmed high-risk melanoma

**PATIENTS WITH COMPLETELY RESECTED HIGH-RISK MELANOMA (N≈1530)**

**INTERVENTION**

R 1:1:1

| Arm 1 | Arm 2 | Arm 3 |
|---|---|---|
| **High-dose fianlimab (IV) + cemiplimab (IV) Q3W** | **Low-dose fianlimab (IV) + cemiplimab (IV) Q3W** | **Pembrolizumab (IV) + placebo (IV) Q3W** |

## Primary Endpoint

Relapse-free survival

## Secondary Endpoints

- Overall survival
- Melanoma-specific survival
- Distant metastasis-free survival
- Quality of life
- Pharmacokinetics
- Safety and tolerability
- Immunogenicity

**FIND OUT MORE**

Scan here to find out more about this study at https://clinicaltrials.gov/ct2/show/NCT05608291

**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.**

IV, intravenous; N, number of patients; Q3W, administered every three weeks; R, randomized.

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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]

- Stage IIC, III, or IV[b] melanoma with complete surgical resection within 12 weeks prior to randomization
- Documented disease-free status within 4 weeks prior to randomization
- ≥12 Aged ≥ 12 years

## SELECTED EXCLUSION CRITERIA[a]

- Uveal melanoma
- Any evidence of residual disease after surgery
- Uncontrolled infection with HIV, hepatitis B virus, or hepatitis C virus infection
- Ongoing or recent (within 2 years) evidence of an autoimmune disease that required systemic treatment with immunosuppressive agents
- <40kg Adolescent patients with body weight < 40kg
- Another malignancy currently progressing or that required active treatment in the last 5 years

**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]Staging is based on AJCC 8th edition.

HIV, human immunodeficiency virus; LAG-3, lymphocyte activation gene-3; PD-1 programmed cell death protein 1.

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.

Current per clinicaltrials.gov as of December 8, 2023.

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