

NCT05608291

PHASE 3 ENROLLING

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

**High-dose fianlimab (IV)
+ cemiplimab (IV)
Q3W**

Arm 2

**Low-dose fianlimab (IV)
+ cemiplimab (IV)
Q3W**

Arm 3

**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 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



Stage IIC, III, or IV melanoma with complete surgical resection within 12 weeks prior to randomization



Disease-free status within 4 weeks prior to randomization



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 evidence of an autoimmune disease that required systemic treatment with immunosuppressive agents



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 844 REGN-MID.
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^aInclusion/exclusion criteria include a summary of selected criteria. Please review the complete study design on [clinicaltrials.gov](https://www.clinicaltrials.gov) for complete details.

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](https://www.clinicaltrials.gov) as of September 29, 2023.

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