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	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 melanoma with complete surgical resection within 12 weeks prior to randomization
- 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 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.
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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.

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 September 29, 2023.

FIA-EM-0009 October 2023.

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