

PLUG-IN: Pembrolizumab Combined With Enfortumab Vedotin for Advanced Melanoma Patients

NCT06906822

Status	RECRUITING
Phase	Phase 2
Sponsor	Grupo Español Multidisciplinar de Melanoma
Enrollment	60 participants

Plain Language Summary

This study is testing whether combining pembrolizumab (an immunotherapy) with enfortumab vedotin (an anti-body-drug that delivers chemotherapy directly to cancer cells) can treat advanced melanoma — a serious form of skin cancer — that can no longer be surgically removed or has spread to other organs.

****You may be eligible if...****

- You are 18 or older
- You have confirmed unresectable (cannot be surgically removed) or metastatic melanoma
- Your cancer has measurable disease that can be tracked on scans
- You are able to use effective contraception during the treatment period if applicable

****You may NOT be eligible if...****

- You have active untreated brain metastases
- You have a serious autoimmune condition requiring long-term steroids
- You have had severe immune-related side effects from prior immunotherapy
- You are pregnant or breastfeeding
- You have significant heart, liver, or kidney problems

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (20)

- Participants are eligible to be included in the study only if all of the following criteria apply:
- Male/female participants who are at least 18 years of age on the day of signing informed consent with histologically confirmed diagnosis of unresectable or metastatic melanoma will be enrolled in this study.
- Participants must have measurable disease by investigator assessment according to RECIST v1.1. Participants with prior definitive radiation therapy must have measurable disease per RECIST v1.1 that is outside the radiation field or has demonstrated unequivocal progression since completion of radiation therapy.
- Male participants:
 - a. A male participant must agree to use a contraception as detailed in Appendix 3 of this protocol during the treatment period and for 9 months after last dose of EV or 4 months after pembrolizumab, whichever occurs last; and refrain from donating sperm during this period.

... and 15 more (see full listing online)

Exclusion (29)

- Participants are excluded from the study if any of the following criteria apply:
- A WOCBP who has a positive urine pregnancy test within 72 hours prior to allocation (see Appendix 3). If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be required.

• Participants who have previously received enfortumab vedotin or other MMAE-based ADCs.

<https://clinicaltrials.gov/study/NCT06906822>
DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).

- Has received prior systemic anti-cancer therapy including investigational agents within 4 weeks prior to the scheduled date of starting the study treatment.
- Has received prior radiotherapy within 2 weeks of start of study intervention or radiation-related toxicities requiring corticosteroids.

... and 24 more (see full listing online)

Locations (13 total)

Complejo Hospitalario Universitario de A Coruña, A Coruña, A Coruña, Spain

Institut Català D'Oncologia - Badalona, Badalona, Barcelona, Spain

Hospital Universitario Marqués de Valdecilla, Santander, Cantabria, Spain

... and 10 more locations