

Mirdametinib in Patients With Advanced NF1-mutant Melanoma

NCT07237100

Status	RECRUITING
Phase	Phase 2
Sponsor	Kevin Kim, MD
Enrollment	10 participants

Plain Language Summary

This study is testing a drug called mirdametinib — which targets a specific mutation (NF1) in tumor cells — for people with advanced melanoma (skin cancer that has spread or cannot be removed) that carries an NF1 gene mutation.

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

- You have unresectable or metastatic melanoma with a confirmed NF1 mutation (tested in a certified lab)
- You have previously been treated with standard immunotherapy drugs (anti-PD-1 and anti-CTLA-4), unless they were not appropriate for you
- Your cancer is currently growing

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

- Your NF1 gene change is of unknown significance
- You have not received prior immunotherapy (unless it was not clinically suitable)
- You are in poor overall health

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

Key Eligibility Criteria

Inclusion (31)

- Patients with unresectable or metastatic melanoma with an NF1 mutation; Variance of NF1 of unknown/ uncertain significance will not be eligible; The genetic analysis for somatic mutations must be performed in a lab that has obtained CLIA certification.
- Patients must have a report of NF1 sequencing analysis performed at CLIA-certified laboratory (by either tissue-based sequencing or liquid biopsy)
- Must have been previously treated with
- anti PD-1/PD-L1 antibody; AND anti CTLA-4 antibody and/or anti LAG3 antibody;
- UNLESS these standard checkpoint inhibitors are not clinically indicated or suitable (for example, comorbid conditions, such as autoimmune disease, or significant toxicity with prior checkpoint inhibitor treatment)

... and 26 more (see full listing online)

Exclusion (17)

- Patients who were previously treated with MEK, ERK or RAF inhibitor therapy
- Patients with symptomatic brain metastasis or active brain lesions ≥ 6 mm size or those who require steroid treatment for brain lesions or leptomeningeal disease
- No systemic cancer therapy within 28 days of the study drug administration,
- Patients must not be simultaneously enrolled in any therapeutic clinical trial
- Patients must not have had investigational therapy administered ≤ 4 weeks, or within a time interval less than at least 5 half-lives of the investigational agent, whichever is longer, prior to the first scheduled day of dosing in this study.

... and 12 more (see full listing online)

Locations (1 total)

<https://clinicaltrials.gov/study/NCT07237100>

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