

Malignant MelanomaMelanoma

A Study to Evaluate the Safety and Activity of Belvarafenib as a Single Agent and in Combination With Either Cobimetinib or Cobimetinib Plus Atezolizumab in Patients With NRAS-mutant Advanced Melanoma.

Trial Status Active, not recruiting	Trial Runs In 5 Countries	Trial Identifier NCT04835805 2020-003674-41 GO42273
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The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase Ib, Open-Label, Multicenter Study to Evaluate the Safety, Pharmacokinetics, and Activity of Belvarafenib as a Single Agent and in Combination With Either Cobimetinib or Cobimetinib Plus Nivolumab in Patients With NRAS-Mutant Advanced Melanoma Who Have Received Anti-PD-1/PD-L1 Therapy

Trial Summary:

This study will evaluate the safety, pharmacokinetics, and activity of belvarafenib as a single agent and in combination with either cobimetinib or cobimetinib plus nivolumab in patients with NRAS-mutant advanced melanoma who have received anti-PD-1/PD-L1 therapy.

Genentech, Inc. Sponsor	Phase 1 Phase
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NCT04835805 2020-003674-41 GO42273
Trial Identifiers

Eligibility Criteria:

Gender All	Age #18 Years	Healthy Volunteers No
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Inclusion Criteria:

- ECOG Performance Status of 0 or 1

ForPatients

by Roche

- Histologically confirmed, metastatic (recurrent or de novo Stage IV) or unresectable locally advanced (Stage III) cutaneous melanoma, that has progressed on or after treatment with anti-PD-1 or anti-PD-L1 therapy. Patients may have received up to two lines of systemic cancer therapy. Treatment with anti-PD-1/PD-L1 in the adjuvant setting is acceptable. Patients must have progressed disease at study entry
- Documentation of NRAS mutation-positive within 5 years prior to screening
- Tumor specimen availability
- Adequate hematologic and end-organ function
- Measurable disease per RECIST v1.1

Exclusion Criteria:

- Prior treatment with a pan-RAF inhibitor
- Treatment with systemic immunotherapy agents (e.g., anti-CTLA4, anti-PD(L)1, cytokine therapy, investigational therapy, etc.) within 28 days prior to C1D1
- Symptomatic, untreated, or actively progressing CNS metastases
- History or signs/symptoms of clinically significant cardiovascular disease
- Known clinically significant liver disease
- History of autoimmune disease or immune deficiency
- Prior treatment with a MEK inhibitor (cobimetinib arm)
- History of or evidence of retinal pathology on ophthalmologic examination (cobimetinib arm)
- History of immune-related AE attributed to prior anti-PD(L)1 therapy that resulted in permanent discontinuation of anti-PD(L)1 therapy (nivolumab arm)