ForPatients
*by Roche*

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 | Trial Runs In | Trial Identifier |
|---|---|---|
| Active, not recruiting | 5 Countries | NCT04835805 2020-003674-41 GO42273 |

*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. | Phase 1 |
|---|---|
| Sponsor | Phase |

**NCT04835805 2020-003674-41 GO42273**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years | No |

## *Inclusion Criteria:*

- ECOG Performance Status of 0 or 1

- 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)