ForPatients
by Roche

Malignant Melanoma

A Study Comparing Vemurafenib Versus Vemurafenib Plus Cobimetinib in Participants With Metastatic Melanoma

Trial Status	Trial Runs In	Trial Identifier
Completed	19 Countries	NCT01689519 2012-003008-11 GO28141

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 III, Double-Blind, Placebo-Controlled Study of Vemurafenib Versus Vemurafenib Plus GDC-0973 in Previously Untreated BRAF^600-Mutation Positive Patients With Unresectable Locally Advanced or Metastatic Melanoma

Trial Summary:

To evaluate the efficacy of vemurafenib in combination with cobimetinib (GDC-0973), compared with vemurafenib and placebo, in previously untreated BRAF V600 mutation-positive patients with unresectable locally advanced or metastatic melanoma, as measured by progression-free survival (PFS), assessed by the study site investigator.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT01689519 2012-003008-11 GO28141
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Participants with histologically confirmed melanoma, either unresectable stage IIIc or stage IV metastatic melanoma, as defined by the American Joint Committee on Cancer 7th edition. Unresectability of stage IIIc disease must have confirmation from a surgical oncologist

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- Participants must be naïve to treatment for locally advanced unresectable or metastatic disease (ie, no prior systemic anti-cancer therapy for advanced disease; stage IIIc and IV). Prior adjuvant immunotherapy (including ipilimumab) is allowed
- Documentation of BRAF V600 mutation-positive status in melanoma tumor tissue (archival or newly obtained tumor samples) using the cobas 4800 BRAF V600 mutation test
- Measurable disease per RECIST v1.1
- Eastern Clinical Oncology Group performance status of 0 or 1
- Consent to provide archival for biomarker analyses
- Consent to undergo tumor biopsies for biomarker analyses
- Life expectancy greater than or equal to (#) 12 weeks
- Adequate hematologic and end organ function

Exclusion Criteria:

- History of prior rapidly accelerated fibrosarcoma or mitogen-activated protein kinase pathway inhibitor treatment
- Palliative radiotherapy within 14 days prior to the first dose of study treatment
- Major surgery or traumatic injury within 14 days prior to first dose of study treatment
- Active malignancy other than melanoma that could potentially interfere with the interpretation of efficacy measures. Participants with a previous malignancy within the past 3 years are excluded except for participants with resected basal cell carcinoma or squamous cell carcinoma of the skin, melanoma in-situ, carcinoma in-situ of the cervix, and carcinoma in-situ of the breast
- History of or evidence of retinal pathology on ophthalmological examination that is considered a risk factor for neurosensory retinal detachment, retinal vein occlusion, or neovascular macular degeneration
- Uncontrolled glaucoma with intraocular pressure
- Serum cholesterol # Grade 2
- Hypertriglyceridemia # Grade 2
- Hyperglycemia (fasting) # Grade 2
- History of clinically significant cardiac dysfunction
- Participants with active central nervous system (CNS) lesions (including carcinomatous meningitis) are excluded. However, participants are eligible if:
- All known CNS lesions have been treated with stereotactic therapy or surgery, AND 2. There has been no evidence of clinical and radiographic disease progression in the CNS for # 3 weeks after radiotherapy or surgery
- Current severe, uncontrolled systemic disease
- History of malabsorption or other condition that would interfere with absorption of study drugs
- Pregnant, lactating, or breast feeding women

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