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CancerNeoplasms

An Extension (Rollover) Study of Vemurafenib in Participants With BRAF V600 Mutation-Positive Malignancies Previously Enrolled in an Antecedent Vemurafenib Protocol

Trial Status	Trial Runs In	Trial Identifier
Completed	25 Countries	NCT01739764 2012-003144-80 GO28399

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:

An Open-Label, Extension (Rollover) Study of Vemurafenib in Patients With BRAF V600 Mutation-Positive Malignancies Previously Enrolled in an Antecedent Vemurafenib Protocol

Trial Summary:

This open-label, multicenter, non-randomized study provided continued access to vemurafenib for eligible participants with BRAF V600 mutation-positive malignancy, who were previously enrolled and treated in an antecedent vemurafenib protocol and did not meet the protocol's criteria for disease progression, or were treated beyond progression and were still deriving clinical benefit (as assessed by investigator), and may have therefore potentially benefited from continued treatment with vemurafenib. Participants received treatment with oral vemurafenib at 960 milligrams (mg) twice daily (BID), 720 mg BID, or 480 mg BID, depending on the last dose in the antecedent protocol. Treatment continued until progression of disease or as long as the participant was deriving clinical benefit, as judged by the investigator (case-by-case decision with approval of the Medical Monitor), death, withdrawal of consent, unacceptable toxicity, loss to follow-up, or decision of the Sponsor to terminate the study, whichever occurred first.

Hoffmann-La Roche	Phase 4
Sponsor	Phase

NCT01739764 2012-003144-80 GO28399
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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All	# 18 Years	No

Inclusion Criteria:

- BRAF V600 mutation-positive malignancy
- Prior eligibility for and on study treatment from an antecedent vemurafenib protocol
- Ability to begin treatment in the extension (rollover) protocol within 15 days following the last day of the study in the antecedent protocol
- Female participants of childbearing potential and male participants with partners of childbearing potential must agree to use 2 adequate methods of contraception as defined by protocol during the course of this study and for at least 6 months after completion of study treatment

Exclusion Criteria:

- Adverse event requiring discontinuation of vemurafenib in the antecedent protocol
- Progressive disease during the antecedent protocol. If approval to treat beyond progression was already given in the antecedent protocol, the participant may roll over into the current protocol without sponsor approval. Under special circumstances, enrollment into this protocol and dosing beyond progression may be considered and will require approval of the sponsor

Participants meeting any of the following exclusion criterion of the antecedent study at the time the participant is considered for the extension (rollover) study:

- Current, recent (within 28 days prior to Day 1), or planned use of any antitumor therapy outside this study
- Any other serious concomitant medical condition that, in the opinion of the investigator, would compromise the safety of the participant or compromise the participant's ability to participate in the study
- History of malabsorption or other clinically significant metabolic dysfunction
- History of clinically significant cardiac or pulmonary dysfunction as specified in antecedent study