ForPatients
by Roche

Metastatic MelanomaSkin Cancer

A Study to Detect V-Raf Murine Sarcoma Viral Oncogene Homolog B1 (BRAF) V600 Mutation on Cell-Free Deoxyribonucleic Acid (cfDNA) From Plasma in Participants With Advanced Melanoma

Trial Status	Trial Runs In	Trial Identifier
Completed	2 Countries	NCT02768207 2015-001731-20 ML29741

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 Single Arm, Open Label, Phase II, Multicenter Study to Assess The Detection of The BRAF V600 Mutation on cfDNA From Plasma in Patients With Advanced Melanoma

Trial Summary:

This is a single arm, multicenter, open label, and non-randomized clinical study on adult participants with unresectable or metastatic melanoma. The study will be conducted in two phases. Pre-screening phase will assess the BRAF V600 mutation in a new mutation analysis triggered by a mutant plasma cfDNA test result. Treatment phase will assess the clinical outcome for the participants treated with vemurafenib plus cobimetinib. The length of the study will be approximately 38 months.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT02768207 2015-001731-20 ML29741
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

Pre-screening phase:

- Participants with histologically confirmed cutaneous melanoma, either unresectable Stage IIIc or Stage IV metastatic melanoma, as defined by American Joint Committee on Cancer 7th edition
- Documentation of BRAF V600 test result mutation-positive status on melanoma tumor tissue using a validated tissue test

Treatment Phase:

- Eastern Cooperative Oncology Group performance status of 0-2
- Adequate hematologic and end organ function obtained within 14 days prior to first dose of study drug treatment
- Negative serum pregnancy test prior to commencement of dosing in women of childbearing potential
- Absence of any psychological, familial, sociological, or geographical condition that potentially hampers compliance with the study protocol and treatment regimen and follow-up after treatment discontinuation schedule
- Female participants of childbearing potential and male participants with partners of childbearing potential must agree to always use two effective forms of contraception during the course of this study and for at least 6 months after completion of study therapy
- Participants should be able to swallow tablets
- Documentation of BRAF mutation positive status in melanoma tissue

Exclusion Criteria:

Treatment Phase:

- History of prior rapidly accelerated fibrosarcoma or mitogen-activated protein kinase pathway inhibitor treatment
- Use of prior chemotherapy or immunotherapy (including treatment with an anti-programmed death 1, or anti- programmed death ligand 1 or anti-cytotoxic T-lymphocyte-associated protein 4 monoclonal antibody) within 4 weeks before first study drug administration
- Palliative radiotherapy within 14 days prior to the first dose of study treatment
- Evidence of retinal pathology on ophthalmologic examination
- Systemic risk factors for retinal vein occlusion
- History of clinically significant cardiac dysfunction
- Current severe, uncontrolled systemic disease
- Pregnancy, lactating or breast feeding
- Intake of St. John's wort or hyperforin (a potent cytochrome P450 3A4 [CYP3A4 enzyme inducer] and grapefruit juice (a potent CYP3A4 enzyme inhibitor) at least 7 days prior to initiation of and during the study treatment