Dabrafenib and/or Trametinib Rollover Study

Last Update: Apr 06, 2025
Open Label, Multi-center Roll-over Study to Assess Long Term Safety in Patients Who Have Completed a Global Novartis or GSK Sponsored Dabrafenib and/or Trametinib Study
ClinicalTrials.gov Identifier:
NCT03340506
Novartis Reference Number:CDRB436X2X02B
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

This study is to provide access for patients who are receiving treatment with dabrafenib and/or trametinib in a Novartis-sponsored Oncology Global Development, Global Medical Affairs or a former GSK-sponsored study who have fulfilled the requirements for the primary objective, and who are judged by the investigator as benefiting from continued treatment in the parent study as judged by the Investigator at the completion of the parent study.

Condition
Melanoma, Non Small Cell Lung Cancer, Solid Tumor, Rare Cancers, High Grade Glioma
Phase
Phase4
Overall Status
Recruiting
Number of Participants
100
Start Date
Dec 28, 2017
Completion Date
Dec 21, 2027
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

dabrafenib

dabrafenib is available in capsules (50mg and 75mg) taken twice a day

Drug

trametinib

trametinib is available in tablets (0.5mg, 2mg dose)

Eligibility Criteria

Inclusion Criteria:

* Patient is currently receiving treatment with dabrafenib/trametinib monotherapy or combination within a Novartis or former GSK sponsored study which has fulfilled the requirements for the primary objective.
* In the opinion of the Investigator would benefit from continued treatment.

Exclusion Criteria:

* Patient has been previously permanently discontinued from study treatment in the parent protocol.
* Patient's indication is commercially available and reimbursed in the local country.
* Patient currently has unresolved toxicities for which dabrafenib and/or trametinib dosing has been interrupted in the parent study.

Spain

Novartis Investigative Site

Recruiting

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Novartis Investigative Site

Recruiting

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Recruiting

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If the location of your choosing does not feature any contact detail, please reach out using the information below.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct03340506*

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