Clinical Study To Further Evaluate The Efficacy Of Dabrafenib Plus Trametinib In Patients With Rare BRAF V600E Mutation-Positive Unresectable or Metastatic Solid Tumors

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ClinicalTrials.gov Identifier:
NCT05868629
Novartis Reference Number:CDRB436IIC01
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 a phase IV, pragmatic single-arm prospective, open label study in pediatric (6 years or older) and adult study participants with rare BRAF V600E mutation-positive unresectable or metastatic solid tumors for whom a decision has already been made to be treated with dabrafenib and trametinib, irrespective of the trial participation.

Condition
Rare Unresectable or Metastatic BRAF V600E Mutation-positive Solid Tumors
Overall Status
Recruiting
Number of Participants
40
Start Date
Feb 06, 2024
Completion Date
May 04, 2028
Gender
All
Age(s)
6 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Other

Non-investigational

Participants obtaining commercial (non-investigational) dabrafenib plus trametinib (i.e. solid formulation or liquid formulation, if approved and commercially available locally) per local guidance or patient access program

Eligibility Criteria

Inclusion Criteria:

* Study participant with a BRAF V600E mutation-positive solid tumor as confirmed by a local laboratory test;
* At least 1 measurable lesion as defined by RECIST v1.1 per local review;
* Study participant previously not treated with dabrafenib and/or trametinib. Study participants who received dabrafenib and trametinib in the past for the treatment of other malignancies are eligible if treatment has been discontinued for greater than 1 year;
* Ability to provide scans for central imaging review

Exclusion Criteria:

* Those with the following tumor types: melanoma, NSCLC, ATC, BTC, glioma and CRC;
* Study participants who have contraindication to receive dabrafenib and/ or trametinib according to the local label;

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Recruiting

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Worldwide Contacts

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

Novartis Pharmaceuticals

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