Effectiveness and Safety of Dabrafenib in Combination With Trametinib as Adjuvant Treatment for Chinese Patients With Stage III BRAF V600 Mutation-positive Melanoma After Complete Resection

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ClinicalTrials.gov Identifier:
NCT04666272
Novartis Reference Number:CDRB436FCN01
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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 is a prospective, open label, single-arm, multicenter, non-interventional study of dabrafenib in combination with trametinib as adjuvant treatment for Chinese patients with stage III BRAF V600 mutation positive melanoma after complete resection. The study will consist of a treatment phase and follow-up phase. The treatment period is 12 months. Discontinuation of study treatment may occur earlier than 12 months for disease recurrence, death, unacceptable toxicity or withdrawal of consent. Patients will be followed for disease recurrence every 6 months and up to 24 months after the end of treatment (EOT)

Condition
Melanoma
Overall Status
Recruiting
Number of Participants
80
Start Date
Dec 31, 2020
Completion Date
Jul 31, 2029
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Interventions

Drug

dabrafenib

There is no treatment allocation. Patients administered dabrafenib alone by prescription that have started before inclusion of the patient into the study could be enrolled.
Drug

trametinib

There is no treatment allocation. Patients administered trametinib alone by prescription that have started before inclusion of the patient into the study could be enrolled.

Eligibility Criteria

Inclusion Criteria:

Patient(s) must meet all of the following criteria to be eligible for inclusion:

1. ≥18 years old of age at the time of informed consent and of Chinese descent
2. Signed written informed consent
3. Going to receive commercial dabrafenib and trametinib according to approved label
4. Completely resected histologically confirmed Stage III BRAF V600 mutation positive cutaneous or mucosal melanoma as defined by the following staging systems:

* for stage III cutaneous melanoma: as per American Joint Committee on Cancer (AJCC) 8th edition for melanoma
* for stage III mucosal melanoma of the head and neck origin: as per AJCC 8th edition for mucosal melanoma of the head and neck
* for stage III mucosal melanoma of anal canal, rectum and genital track origin: as per Chinese guidelines on the diagnosis and treatment of melanoma 2019 edition
5. Must be surgically rendered free of disease (defined as the date of the most recent surgery) no more than 12 weeks before enrollment
6. Recovered from definitive surgery (e.g. no uncontrolled wound infections or indwelling drains)
7. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-1

Exclusion Criteria:

Patient will be excluded from this study if he/she meets any of the following criteria:

1. Known ocular melanoma
2. Patient received other systemic neo-adjuvant and/or adjuvant therapy for melanoma (including dabrafenib in combination with trametinib started before ICF signature)
3. Patient is not able to comply with the planned study procedures
4. Taken an investigational drug within 28 days prior to enrolment
5. History of another malignancy (including melanoma) or a concurrent malignancy, except malignancies that were treated curatively and have not recurred within 2 years prior to treatment.

China

Novartis Investigative Site

Recruiting

Fuzhou,Fujian,350013,China

Novartis Investigative Site

Recruiting

Beijing,100036,China

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Recruiting

Zhengzhou,Henan,410100,China

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Recruiting

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Changsha,Hunan,410013,China

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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.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct04666272*

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