Special Drug Use-results Surveillance of Tafinlar/Mekinist

Last Update: Jan 14, 2025
Observational Study to Assess Safety and Effectiveness of Dabrafenib and Trametinib in Patients With BRAF V600E Mutation-positive Unresectable Advanced or Recurrent Solid Tumor
ClinicalTrials.gov Identifier:
NCT06262919
Novartis Reference Number:CDRB436I1401
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 is a prospective, multicenter, single-arm, non-interventional and observational J-PMS conducted by the central registration system and operated in Electronic data capture. In the Post-Marketing Surveillance (PMS), dabrafenib and trametinib are used as the marketed drugs. Registration of the corresponding patients is to be conducted by the central registered system under current medical practice.

Target number of adult patient is 65 (as the number of patients in the effectiveness analysis set).

Target number of pediatric patient is not determined. Estimated number of enrolled patients is approximately 20 (as the number of patients in the enrolled set)

The observation period for pediatric patients will last after the start of treatment until 8 years (planned, November 2031) after the approval of additional indications, regardless of discontinuation of the product, in order to collect long-term information from as many patients as possible during the reexamination period. The duration of observation for adult patients will be 1 year after the start of treatment with the product.

Condition
BRAF V600E Mutation-positive Unresectable Advanced or Recurrent Solid Tumor
Overall Status
Recruiting
Number of Participants
110
Start Date
Feb 09, 2024
Completion Date
Dec 31, 2031
Gender
All
Age(s)
6 Years - 99 Years (Child, Adult, Older Adult)

Interventions

Drug

Tafinlar/Mekinist

There is no treatment allocation. Patients administered Tafinlar/Mekinist by prescription that have started before inclusion of the patient into the study will be enrolled.

Eligibility Criteria

Inclusion Criteria:

1. Patients who have given written consent to cooperate in this surveillance
2. For patients aged \< 18 years at the start of treatment with the product, their legally authorized representative must have given written informed consent for cooperation in this surveillance prior to patient enrollment.
3. Patients who start treatment with the product for BRAF-mutation-positive advanced/recurrent solid tumors (excluding colorectal cancer) after the approval of additional indications

Exclusion Criteria:

1. Patients who have received or are receiving a product containing the same ingredient as the product in any other study or research than this surveillance
2. Patients with BRAF-mutation-positive malignant melanoma
3. Patients with BRAF-mutation-positive non-small cell lung cancer
4. Patients with BRAF-mutation-positive hairy cell leukemia

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