PrOspective Non-interventional study in patients with locally advanced or metastatic TRK fusion cancer treated with larotrectinib (ON-TRK)

First published: 20/11/2019

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Study Ongoing

Administrative details

EU PAS number

EUPAS32136

Study ID

44357

DARWIN EU® study

No

Study countries

- ☐ Argentina
- ☐ Australia
- ☐ Austria

- [ ] Belgium
- [ ] Brazil
- [ ] Canada
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Korea, Republic of
- [ ] Luxembourg
- [ ] Norway
- [ ] Russian Federation
- [ ] Spain
- [ ] Switzerland
- [ ] Taiwan
- [ ] United Kingdom
- [ ] United States

Study description

In this observational study researcher want to learn more about the effectiveness of drug VITRAKVI (generic name: larotrectinib) and how well the drug is tolerated during routine use in patients with TRK fusion cancer which is locally advanced or spread from the place where it started to other places in the body. TRK fusion cancer is a term used to describe a variety of common and rare cancers that are caused by a change to the NTRK (Neurotrophic Tyrosine Kinase) gene called a fusion. During this fusion, an NTRK gene joins together, or fuses, with a different gene. This joining results in the activation of certain proteins (TRK fusion proteins), which can cause cancer cells to multiply and form a tumor. VITRAKVI is an approved drug that blocks the action of the NTRK

gene fusion. This study will enroll adult and paediatric patients suffering from a solid tumor with NTRK gene fusion for whom the decision to treat their disease with VITRAKVI has been made by their treating physicians. During the study, patients' medical information such as treatment information with VITRAKVI, other medication or treatments, changes in disease status and other health signs and symptoms will be collected within the normal medical care by the treating doctor. Participants will be observed over a period from 24 to 60 months.

Study status

Ongoing

Research institutions and networks

Institutions

Bayer AG

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Institution

Contact details

Study institution contact

Bayer Clinical Trials BAYER AG clinical-trials-contact@bayer.com

Study contact

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Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/08/2019

Study start date

Planned: 30/03/2020

Actual: 03/04/2020

Date of final study report

Planned: 30/06/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

20324_Study Protocol_V2.0_2019-09-04_Redacted.pdf(5.31 MB)

20324_Study Protocol_Redacted_V3.1_2022-11-11.pdf(886.97 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

NCT04142437

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

The primary objective of this study is to describe the safety of larotrectinib in adult and pediatric patients with locally advanced or metastatic TRK fusion cancer, including incidences of all treatment-emergent adverse events (TEAEs) in real-world practice conditions

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

VITRAKVI

Medical condition to be studied

NTRK gene fusion overexpression

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

300

Study design details

Outcomes

1. Number of participants with treatmentemergent adverse events (TEAEs), 2. Severity of TEAEs, 3. Seriousness of TEAEs, 4. Outcome of TEAEs, 5. Causality of TEAEs, 6. Action taken related to larotrectinib treatment. 1. ORR, 2. PFS, 3. OS, 4. (Pediatric cohort) Change in height and weight from baseline by visit, developmental milestones abnormalities and tanner stage abnormalities, 5. Neurological abnormalities, 6. Total dose, starting and ending dose, dose modification during treatment and duration of treatment, 7. DCR, 8. DOR, 9. TTR, 10. ORR,DCR,DOR,TTR,PFS,OS by patient subgroup(s).

Data analysis plan

Statistical analyses will be of explorative and descriptive nature. The study is not designed to support any formal statistical testing. Unless otherwise stated, all CIs will be given at a 2-sided 95% level. All variables will be analyzed descriptively with appropriate statistical methods: categorical variables by frequency tables and continuous variables by sample statistics. Patients who took at least one dose of larotrectinib will be included in the safety analysis set. Patients who took at least one dose of larotrectinib, did not violate a major inclusion/exclusion criterion, and had at least one post baseline assessment

after receiving larotrectinib will be included in the full analysis set. Safety data will be analyzed on the safety analysis set, effectiveness data on the full analysis set. Demographic and baseline data will be described for both full and safety analysis sets.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No