A non-interventional, multi-national, multi-center post authorization safety study (PASS) to assess the long term safety and tolerability of Odomzo (sonidegib) administered in patients with locally advanced cell carcinoma (laBCC). (PASS ODOMZO (Sonidegib))

First published: 05/07/2019

Last updated: 14/03/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/37938

EU PAS number

EUPAS28453

Study ID

37938

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Spain
- [ ] Switzerland

Study description

Collect real world safety data on the use of sonidegib in adult patients with laBCC. Document major safety parameters such as on treatment deaths, adverse events (AEs)/ serious adverse events (SAEs) and discontinuation secondary to AEs.

Study status

Ongoing

Research institutions and networks

Institutions

Haut-Tumor-Zentrum Hannover

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Helios Klinikum Erfurt Erfurt, Germany, Harzklinikum Quedlinburg Quedinburg, Germany, Fachklinik Muenster-Hornheide Münster, Germany, Helios St. Elisabeth Klinik Oberhausen Oberhausen, Germany, SRH Wald-Klinikum Oberhausen Oberhausen, Germany, UKSH, Christian-Albrechts-Universitaet zu Kiel Kiel, Gemany, Elbe Klinikum Buxtehude Buxtehude, Germany, Universitaets-Hautklinik Tuebingen Tübingen, Germany, UKSH, Klinik fuer Dermatologie, Campus Luebeck Lübeck, Germany, NCI France

Contact details

Study institution contact

Ralf Gutzmer

Study contact

Roxana.Dragusel@sunpharma.com

Primary lead investigator

Ralf Gutzmer

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/11/2018

Actual: 01/11/2018

Study start date
Planned: 01/11/2018

Actual: 01/11/2018

Data analysis start date
Planned: 01/11/2024

Date of final study report
Planned: 01/11/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sun Pharmaceutical Industries Ltd

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Other study registration identification numbers and links

PASS MEA 21.3

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

1. Collect real-world safety data on the use of sonidegib in adult patients with laBCC2. Document major safety parameters such as on-treatment deaths, adverse events (AEs)/serious adverse events (SAEs), and discontinuation secondary to AEs.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

SONIDEGIB

Medical condition to be studied

Basal cell carcinoma

Population studied

Age groups

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Estimated number of subjects

300

Study design details

Outcomes

Proportion of patients with AEs/SAEs including on treatment deaths and discontinuation due to AEs/SAEs, Proportion of patients with AEs of special interest (AESI) or populations, in pateints with:• relevant polymorphism• ≥65 yrs.• hepatic or renal impairment• Female patients with child bearing potential using anticonceptives• anemia (hemoglobin <9 g/dL), recent myocardial ischemia or cardiac failure• concomitant medications with known risk of creatine kinase elevation

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Data analysis plan

Descriptive summaries and listings of the data will be provided for yearly status update and safety reports.The final analysis will be performed when the last patient has completed the 3 year observation period after enrollment, or discontinued earlier, whichever comes first, primary, secondary and exploratory endpoints will be analyzed at this time point.

Data management

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