Physicians’ knowledge on the risks associated with Odomzo® exposure after the implementation of a risk minimization program (CLDE225A2405)

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Study Planned

Administrative details

EU PAS number

EUPAS35766

Study ID

40159

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Italy

☐ Spain

Study description

Physicians’ knowledge on the risks associated with Odomzo® exposure after the implementation of a risk minimization program In order to minimize the risks associated with sonidegib exposure, Sun Pharma is implementing a pregnancy prevention program (PPP) as an additional risk minimization measure (aRMM) to reduce the likelihood that women of childbearing potential become pregnant while taking sonidegib, are prescribed sonidegib during pregnancy, or are exposed to sonidegib during pregnancy by their male partners while they are being treated. In addition, information about the potential effect of sonidegib on fertility is also included in the educational materials. The PPP consists of educational materials that comprise a Dear Healthcare Professional (DHCP) letter and separate HCP and patient educational brochures integrated with reminder cards. The DHCP letter, HCP brochure and copies of the Patient brochures will all be distributed at launch. HCPs should obtain additional patient educational materials as required from their local Sun Pharma representative. Furthermore, new prescribers will obtain copies of the educational materials from their local Sun Pharma representative. The effectiveness of the Odomzo® PPP will be measured on a country-specific level, in agreement with National Competent Authorities. This non-interventional study is a physician survey on their knowledge of the risks associated with sonidegib. It will be run in countries where surveys are considered an appropriate way to measure the effectiveness of the Odomzo® PPP, and is pending the agreement from National Competent Authorities. Participation in this study is optional for each country, and countries may implement alternative measures to assess the effectiveness of the Odomzo® PPP.

Study status

Planned

Contact details

Study institution contact

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Study contact

Roxana.Dragusel@sunpharma.com

Primary lead investigator

Roxana Dragusel

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2019

Study start date

Planned: 01/03/2019

Data analysis start date

Planned: 01/09/2019

Date of interim report, if expected

Planned: 01/12/2019

Date of final study report

Planned: 01/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sun Pharmaceutical Industries Europe BV

Study protocol

20180130 Odomzo - Risk Management Plan Effectiveness Protocol_v2.pdf
(443.08 KB)

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

CLE225A2405

Methodological aspects

Study type

Study type list

Study type:

Not applicable

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

Asessment of Physician's knowledge on the risks associated with Odomzo

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

5

Study design details

Outcomes

Primary objective: -To assess HCPs’ knowledge on the risk of teratogenicity associated with sonidegib exposure during pregnancy and impaired fertility after the delivery of the HCP educational materials including the DHCP letter. Secondary objective: To evaluate the delivery of educational materials to HCPs consisting of DCHP letter and HCP educational brochure.

Data analysis plan

Milestones Dates when data collection starts and ends, and also final study reports dates will vary between the countries where the study is conducted and will depend on Odomzo®'s National Competent Authorities approval. Start of data collection: approximately one year after the drug is locally approved and available for prescription End of data collection: six months of local data collection. This may be extended to 12 months, if relevant data collection is not possible within 6 months, e.g. if more followup/reminders are needed in case of a low response rate Final report of study results: one year after the end of data collection in all countries which participate in this survey. Date of final study report submission Final study report: - one year after the end of data collection in all countries which participate in this survey

Documents

Study results

20191216 DE- Odomzo - Risk Management Plan Effectiveness results vF.PDF (2.78 MB)

2020723 FR Odomzo - Risk Management Plan Effectiveness results_France.pdf (508.46 KB)

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

Questionnaire to be filled out voluntarily

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