Survey to Assess the Effectiveness of Ponvory® Educational Materials for Additional Risk Minimization Measures in the European Union

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/107764

EU PAS number

EUPAS107763

Study ID

107764

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Belgium
- ☐ Czechia
- ☐ France
- ☐ Germany
- ☐ Italy
- ☐ Netherlands
- ☐ Spain
- ☐ United Kingdom

Study status

Ongoing

Research institutions and networks

Institutions

Laboratoires Juvisé Pharmaceuticals

Contact details

Study institution contact

Aurélie BILLARD

Study contact

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Primary lead investigator

Aurélie BILLARD

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 21/12/2022

Actual: 21/12/2022

Study start date
Planned: 08/01/2024

Actual: 27/03/2024

Date of final study report
Planned: 30/06/2025

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)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Not applicable

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Knowledge and understanding for the management of Ponvory risks

Study drug and medical condition

Name of medicine

PONVORY

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

PONESIMOD

Anatomical Therapeutic Chemical (ATC) code

(L04AA50) ponesimod

ponesimod

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)

Estimated number of subjects

355

Study design details

Outcomes

Knowledge and understanding for the management of Ponvory risks, receipt and awareness of the educational materials.

Data analysis plan

The third-party vendor will perform rigorous ‘real-time’ checks to ensure that the data collected are valid and of a high quality. Inbuilt quality control within the surveys will minimize the opportunity for missing data. Data analysis will be performed by the third-party vendor. A minimum total score of ≥80% of correct responses on all survey questions will be considered indicative of satisfactory effectiveness. The threshold of success refers to the proportion of correct responses at each survey question. Achieving ≥80% correct responses to each question represents a sizeable majority. Summary results for the overall response rate and 95% CI will be presented separately for HCPs and patients/caregivers.

Data management

Data sources

Data sources (types)

Other

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