Post-authorization Safety Study: Ponesimod Pregnancy Outcomes Program Utilizing Enhanced Pharmacovigilance Monitoring (POEM)

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Study Ongoing

Administrative details

EU PAS number

EUPAS50031

Study ID

50061

DARWIN EU® study

No

Study countries

Austria

Belgium

Bulgaria

Canada
Croatia
Cyprus
Czechia
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Luxembourg
Malta
Netherlands
Poland
Portugal
Romania
Slovakia
Slovenia
Spain
Sweden
United Kingdom
United States

Study status

Ongoing

Research institutions and networks

Institutions

Laboratoires Juvisé Pharmaceuticals

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Bruno POULY

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/03/2020

Study start date

Planned: 01/06/2023

Actual: 06/01/2023

Date of final study report

Planned: 29/05/2032

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

This study aims to evaluate the potential risk of reproductive and embryofetal toxicity in pregnant women exposed to ponesimod.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Enhanced pharmacovigilance program

Study drug and medical condition

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

PONESIMOD

Anatomical Therapeutic Chemical (ATC) code

(L04AA50) ponesimod

ponesimod

Medical condition to be studied

Multiple sclerosis

Premature baby

Congenital anomaly

Abortion spontaneous

Abortion induced

Ectopic pregnancy

Anembryonic gestation

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

500

Study design details

Outcomes

Estimate the proportion of major congenital malformations (according to EUROCAT classification) associated with exposure to ponesimod, immediately before (up to 1 week prior to last menstrual period LMP) and during pregnancy in live births, and in the group of live births, still births and termination of pregnancy for fetal anomaly (TOPFA). Characterize the proportion of major congenital malformations by the MedDRA system organ classes (SOCs). Estimate the proportion of minor congenital malformations (according to EUROCAT classification standards) associated with exposure to ponesimod, immediately before (up to 1 week prior to LMP) and during pregnancy in live births, and in the group of live births, still births and TOPFA.

Data analysis plan

No formal statistical hypothesis testing is planned. All summaries and analyses will be of a descriptive nature. Descriptive statistics with corresponding 95%

confidence intervals using Clopper-Pearson (exact) method will be the main statistical methodology, eg: • continuous variables, will be summarized using number of participants (n), mean, standard deviation, median, minimum, and maximum. • categorical variables will be summarized for each category with number of participants and percentages. • the number of missing values will be displayed for all variables

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

Spontaneous reports of suspected adverse drug reactions

Data sources (types), other

Prospective patient-based data collection, Enhanced pharmacovigilance monitoring

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