Post-Authorization Safety Study for Assessment of Pregnancy Outcomes in Patients Treated with Mayzent (siponimod): An OTIS Observational Pregnancy Surveillance Study

First published: 21/06/2021

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Study Ongoing

Administrative details

EU PAS number

EUPAS41495

Study ID

43835

DARWIN EU® study

No

Study countries

Canada

United States

Study description

The study aims to evaluate risk of adverse pregnancy or infant outcomes in patients exposed to Mayzent/siponimod therapy during pregnancy. This study will utilize a prospective, observational, exposure cohort design and conducted by the Organization of Teratology Information Specialists (OTIS) Research Group, a network of university and health department based telephone information centers serving pregnant women and healthcare providers throughout North America. The primary objective is to estimate and compare the prevalence of major structural defects in siponimod exposed pregnant women versus 1) disease-matched pregnant women not exposed to siponimod, and 2) healthy pregnant women.

Study status

Ongoing

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Networks

Organization of Teratology Information Specialists (OTIS) Network

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Network

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

trialandresults.registries@novartis.com

Study contact

trialandresults.registries@novartis.com

Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/03/2020

Actual: 05/03/2020

Study start date

Planned: 16/12/2021

Actual: 15/12/2021

Data analysis start date
Planned: 31/05/2032

Date of final study report
Planned: 31/05/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharmaceuticals

Study protocol

BAF312A2403 - final draft 3 protocol - for submission - Clean version_Redacted.pdf (1.05 MB)

BAF312A2403 - final protocol V1.1 - for submission - Clean_Redacted.pdf (940.31 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

CBAF312A2403

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 is to estimate and compare the prevalence of major structural defects in siponimod exposed pregnant women versus 1) disease-matched pregnant women not exposed to siponimod, and 2) healthy pregnant women.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

MAYZENT

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

SIPONIMOD

Anatomical Therapeutic Chemical (ATC) code

(L04AA42) siponimod

siponimod

Medical condition to be studied

Multiple sclerosis

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)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)

- Adults (85 years and over)

Special population of interest

Pregnant women

Estimated number of subjects

867

Study design details

Outcomes

The primary outcome of the study is major structural defects.

Secondary outcomes:
- Spontaneous abortion/miscarriage.
- Stillbirth.
- Elective termination.
- Preterm delivery.
- Preeclampsia / eclampsia.
- Pattern of 3 or more minor structural defects.
- Small for gestational age.
- Postnatal growth small for age at approximately one year of age.
- Developmental performance at approximately one year of age.
- Serious or opportunistic infections in the first year of life.

Data analysis plan

The primary population for analysis will be those enrolled in the prospective cohort study comparing siponimod-exposed pregnancies with MS to the disease-matched cohort and the non-diseased cohort. Statistical analyses of those enrolled in the exposure series who do not meet the cohort study criteria

will be descriptive only. All relevant exposure, outcome, and covariate data within each study group will be summarized using descriptive statistics annually. Means and standard deviations will be presented for continuous variables and frequencies and percentages will be presented for categorical variables. At the completion of the study, a final analysis with adjusted comparisons between cohort groups will be performed.

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)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection, exposure registry

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