

# 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

**Last updated:** 18/07/2024

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.

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## Study status

Ongoing

# Research institutions and networks

## Institutions

**Novartis Pharmaceuticals**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Networks

# Organization of Teratology Information Specialists (OTIS) Network

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Network

## Contact details

### Study institution contact

Novartis Clinical Disclosure Officer  
trialandresults.registries@novartis.com

Study contact

[trialandresults.registries@novartis.com](mailto: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

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### Study start date

Planned: 16/12/2021

Actual: 15/12/2021

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### **Data analysis start date**

Planned: 31/05/2032

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### **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

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## 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

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#### **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

### Name of medicine

MAYZENT

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

SIPONIMOD

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### Anatomical Therapeutic Chemical (ATC) code

(L04AA42) siponimod

siponimod

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### 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)

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### **Special population of interest**

Pregnant women

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### **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.
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### **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](#)

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

### Data characterisation conducted

No