

# Satralizumab Single-Arm Pregnancy Safety Study: A Global, Observational, Single-Arm, 10-Year Study of Pregnancy and Infant Outcomes in Satralizumab-Exposed Women With Neuromyelitis Optica Spectrum Disorder

**First published:** 04/07/2022

**Last updated:** 14/03/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS47980

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### Study ID

47981

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### DARWIN EU® study

No

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### Study countries

- Canada
  - France
  - Germany
  - Italy
  - United States
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### **Study description**

This is a global, non-interventional, single-arm, 10-year study on the safety of satralizumab in women with Neuromyelitis Optica Spectrum Disorder (NMOSD) and their infants exposed to the study drug during the 6 months prior to the last menstrual period (LMP) or at any time during the pregnancy. The study will collect primary data from satralizumab-exposed pregnant women, their obstetric provider, and their satralizumab prescriber, as well as from the infant's health care provider (HCP) throughout the first year of life for live births. Maternal, fetal, and infant adverse outcomes will be described.

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### **Study status**

Ongoing

## Contact details

### **Study institution contact**

Thomas Paul Leist [global.clinical\\_trial\\_registry@roche.com](mailto:global.clinical_trial_registry@roche.com)

**Study contact**

[global.clinical\\_trial\\_registry@roche.com](mailto:global.clinical_trial_registry@roche.com)

### **Primary lead investigator**

Thomas Paul Leist

**Primary lead investigator**

# Study timelines

## **Date when funding contract was signed**

Planned: 15/08/2022

Actual: 15/08/2022

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## **Study start date**

Planned: 01/09/2022

Actual: 22/11/2022

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## **Date of final study report**

Planned: 31/12/2033

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Hoffmann-La Roche

# Study protocol

[study-wn42856\\_Redacted.pdf](#) (1.35 MB)

# Regulatory

## **Was the study required by a regulatory body?**

Yes

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

WN42856

### Methodological aspects

#### Study type

#### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

**Main study objective:**

The main objective of the study is to collect and describe maternal, fetal, and infant adverse outcomes among women with neuromyelitis optica spectrum disorder (NMOSD) exposed to satralizumab during the 6 months prior to the last menstrual period (LMP) or at any time during pregnancy.

#### Study Design

## **Non-interventional study design**

Cohort

Other

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## **Non-interventional study design, other**

Single-arm, Non-interventional pregnancy safety study

# Study drug and medical condition

## **Medicinal product name**

ENSPRYNG

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## **Medical condition to be studied**

Neuromyelitis optica spectrum disorder

# Population studied

## **Age groups**

- Adolescents (12 to < 18 years)
  - Infants and toddlers (28 days - 23 months)
  - Preterm newborn infants (0 - 27 days)
  - Term newborn infants (0 - 27 days)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
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## **Special population of interest**

Pregnant women

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## **Estimated number of subjects**

## Study design details

### **Outcomes**

To observe and report selected adverse pregnancy and birth outcomes and pregnancy complications in women with NMOSD exposed to satralizumab during a defined exposure window, and to observe and report selected adverse fetal/neonatal/infant outcomes at birth and through the first year of life of infants from pregnancies in women with NMOSD exposed to satralizumab during the defined exposure window.

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### **Data analysis plan**

Descriptive analyses will be performed to gain an understanding of the qualitative and quantitative nature of the data collected and the characteristics of the study sample. If there are sufficient numbers of subjects enrolled in the pregnancy safety study, descriptive statistics will be reported using summary tables and figures (where appropriate). Continuous variables will be summarized using mean, standard deviation, range (min-max), median and interquartile range. Categorical variables will be summarized using counts and proportions (%). The number of subjects with non-missing data will be presented.

## 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

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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