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

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47981

EU PAS number

EUPAS47980

Study ID

47981

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] United States

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.

Study status

Ongoing

Contact details

Study institution contact

Thomas Paul Leist

Study contact

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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

Study start date

Planned: 01/09/2022

Actual: 22/11/2022

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

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

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

Non-interventional study design, other

Single-arm, Non-interventional pregnancy safety study

Study drug and medical condition

Name of medicine

ENSPRYNG

Medical condition to be studied

Neuromyelitis optica spectrum disorder

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

60

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.

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

Data sources

Data sources (types)

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