An Observational Pregnancy Safety Study in Women with Neuromyelitis Optica Spectrum Disorder (NMOSD) Exposed to UPLIZNA® (inebilizumab-cdon) during Pregnancy (VIB0551.P4.S4 /20230064)

First published: 29/06/2023

Last updated: 02/04/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS105613

Study ID

105845

DARWIN EU® study

No

Study countries

- ☐ Canada
- ☐ Denmark

- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Norway
- [ ] Sweden
- [ ] United States

Study description

This global observational pregnancy safety study is conducted to better characterize how inebilizumab commercial product (UPLIZNA) may affect pregnancy and infant outcomes.

The study is a post-marketing commitment that aims to monitor female patients who were exposed to UPLIZNA during pregnancy, as defined by receipt of any dose during pregnancy or within 6 months preceding conception. The primary objectives are: (1) to assess pregnancy and birth outcomes in female patients with neuromyelitis optica spectrum disorder (NMOSD), exposed to inebilizumab commercial product (UPLIZNA) during pregnancy as defined by receipt of any dose during pregnancy or within 6 months preceding conception, (2) to describe major congenital malformations, minor congenital malformations, spontaneous abortions, stillbirths, preterm births, and small-for-gestational-age births, if they occur, in women with gestational exposure to UPLIZNA.

The study period is a minimum 10 years.

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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Study contact

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Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 11/11/2022

Study start date

Planned: 01/07/2023

Actual: 10/07/2023

Data analysis start date
Planned: 16/02/2033

Date of interim report, if expected
Planned: 31/07/2026

Date of final study report
Planned: 31/07/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Horizon Therapeutics

Study protocol

Protocol-Published Original inebilizumab-cdon 20230064 .pdf (452.31 KB)

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

VIB0551.P4.S4

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:

To assess pregnancy and birth outcomes in female patients with neuromyelitis optica spectrum disorder (NMOSD), exposed to UPLIZNA during pregnancy as defined by receipt of any dose during pregnancy or within 6 months preceding conception.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational Pregnancy Safety Study

Study drug and medical condition

Name of medicine

UPLIZNA

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

INEBILIZUMAB

Medical condition to be studied

Neuromyelitis optica spectrum disorder

Population studied

Short description of the study population

Study is recruiting participants ages 15 years and older.

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

• Major congenital malformation (MCM): Any major structural or chromosomal defect, or a combination of 2 or more conditional defects in live-born infants, stillbirths, or fetal losses of any gestational age (including outcomes prior to 20 weeks' gestation or weighing < 500 g)
• Preterm birth: An infant born at gestational age < 37 weeks
• Low birth weight: An infant whose birth weight < 2500 g.
• Minor congenital malformation: congenital anomalies that do not require major medical or surgical treatment, do not seriously affect health and development, and do not have significant cosmetic impact, in live-born infants, stillbirths, or fetal losses of any gestational age.
• Developmental milestones or neurologic abnormalities in offspring of exposed mothers.
• Abnormalities of immune system development in offspring of exposed mothers.

Data analysis plan

Pregnancy outcomes will be summarized by the trimester of exposure and by preconception exposure.
The number of infants with congenital malformations will be summarized

descriptively.
In addition, the risk of infants with congenital malformations, defined as the percentage of infants with congenital malformations among total number of infants, will be reported.
If data permit, analyses will also be presented by the subgroups of maternal age, race/ethnicity, prior history of elective or therapeutic pregnancy termination status, prospective cases vs. retrospective cases, and other important risk factors.

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

Data sources (types), other

Prospective patient-based data collection, Data will also be collected on retrospective cases as well (among patients whose pregnancy outcome has been identified). The data will be collected at enrollment, and if the infant is less than 12 month-old, the infant will be followed up to 12 months after

delivery

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