Nipocalimab Pregnancy Enhanced Tracking with Neonatal and Infant Assessment (PETUNIA)

First published: 11/11/2026

Last updated: 11/11/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000001173

Study ID

1000001173

DARWIN EU® study

No

Study countries

- Austria
- Bahrain
- Belgium
- Brazil

- Bulgaria
- Canada
- China
- Croatia
- Cyprus
- Czechia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Guinea-Bissau
- Hungary
- Ireland
- Israel
- Italy
- Japan
- Korea, Republic of
- Latvia
- Lithuania
- Luxembourg
- Malta
- Mexico
- Netherlands
- Norway
- Poland
- Portugal
- Qatar
- Romania

Saudi Arabia
Slovakia
Slovenia
Spain
Sweden
Switzerland
United Arab Emirates
United Kingdom
United States

Study description

This is a global, non-interventional study using a single-arm design to determine the prevalence of various maternal, pregnancy, neonatal, and infant outcomes after exposure to nipocalimab immediately before or during pregnancy. The program is based on a secondary use of data collected via enhanced pharmacovigilance monitoring within the Company global safety database. Enhanced monitoring will utilize prospective and retrospective cases reported to the company global safety database from post-marketing reports, performed using targeted follow-up questionnaires. Inclusion in the program will start at the initial report to the safety database of exposure to nipocalimab in pregnancy and will cover the duration of pregnancy and through 12 months of life for the infant. Prospective and retrospective case reports from April 29, 2025 will be followed-up in the program.

Study status

Planned

Research institutions and networks

Institutions

Johnson & Johnson

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Melanie Jacobson

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/11/2026

Actual: 06/11/2026

Study start date

Planned: 30/11/2026

Data analysis start date
Planned: 30/10/2028

Date of interim report, if expected
Planned: 30/04/2029

Date of final study report
Planned: 30/10/2036

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Johnson & Johnson global safety database

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

Enhanced pharmacovigilance program.

Main study objective:

The objective of this study is to estimate the prevalence of adverse pregnancy outcomes, maternal complications, and neonatal and infant health outcomes (up to one year of age) among individuals exposed to nipocalimab immediately before (up to 1 week [7 days] prior to the estimated date of conception) or during pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

IMAAVY

Anatomical Therapeutic Chemical (ATC) code

(L04AL03) Nipocalimab

Nipocalimab

Medical condition to be studied

Pregnancy

High risk pregnancy

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

Special population of interest, other

Pregnant participants exposed to nipocalimab within 1 week (7 days) before or during pregnancy.

Estimated number of subjects

Study design details

Outcomes

Study endpoints include:

- Fetal growth restriction
- Small for gestational age
- Hypertensive disorders of pregnancy
- Placental abruption
- Serious infections in neonates
- Serious infections in infants
- Non-chromosomal major congenital malformations
- Live birth
- Spontaneous abortion
- Stillbirth
- Preterm birth
- Intrapartum hemorrhage
- Postpartum hemorrhage
- Neonatal death
- Infant death

Data analysis plan

All analyses will be descriptive and will not test formal statistical hypotheses. Nipocalimab-exposed pregnancies will be described across demographic and clinical characteristics. The number of pregnancies exposed to nipocalimab by trimester will be summarized. Outcomes of interest will be reported as proportions (the number with each outcome divided by the total number of pregnancies/mothers/neonates/infants with known outcome, as appropriate) with 95% confidence intervals.

Data management

Data source(s), other

Spontaneous reports of suspected adverse drug reactions

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