Pregnancy Enhanced Tracking with Neonatal and Infant Assessment (PETUNIA): Design of a Safety Study for Nipocalimab in Generalized Myasthenia Gravis

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This plain language summary infographic was prepared from an encore poster presented at the 27th Annual Neuromuscular Study Group (NMSG) Scientific Meeting (San Antonio, TX, USA; September 25–27, 2026).

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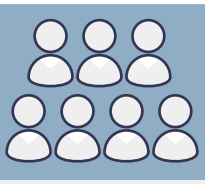
PETUNIA

WHAT IS MYASTHENIA GRAVIS (MG)?

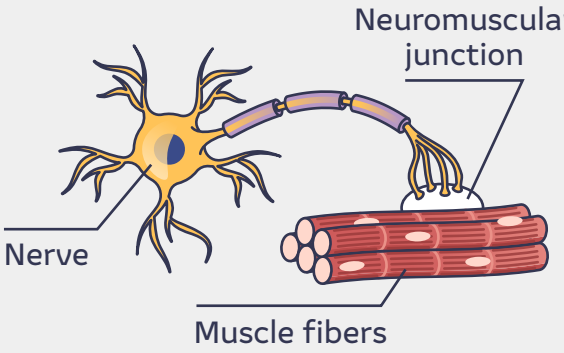
MG is a rare, chronic autoimmune disease that affects approximately **700,000** people worldwide[1]



Symptoms typically start as **eye-related** (i.e., droopy eyelids, double vision), but the disease often progresses to **generalized MG (gMG)** where **other muscle groups** across the body are affected, such as those used for **talking, chewing,** and even **breathing**[1,3]

gMG frequently affects people who can become **pregnant**[4]

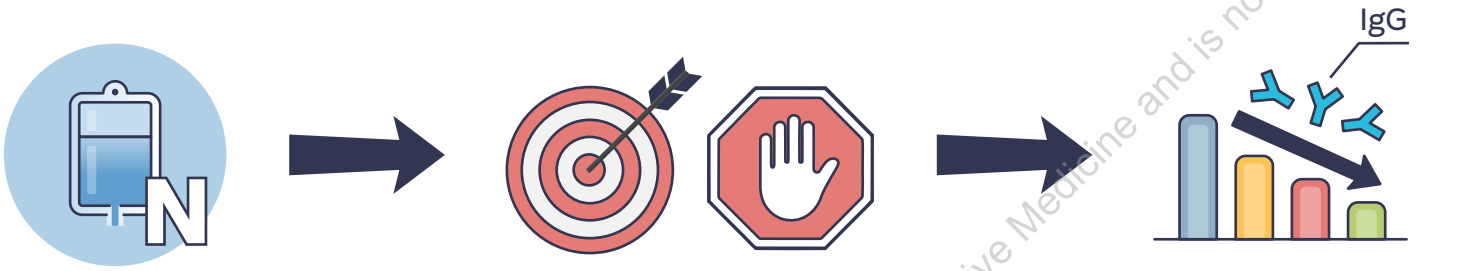
It happens when the body's **immune system mistakenly attacks** its own **muscles at the neuromuscular junction**, leading to **muscle weakness** that worsens with activity and improves with rest[1,2]



WHAT IS NIPOCALIMAB?

Nipocalimab is a medicine used to treat gMG; it is **approved** in the **United States**, **Europe**, and many other countries **worldwide**[5,6]

It works by blocking a specific part of the immune system called the **neonatal Fc receptor (FcRn)** to reduce the amount of **immunoglobulin G (IgG)** antibodies in the body, including the harmful **IgG** that can play a role in **gMG**[7]



Nipocalimab **Targets and blocks FcRn** **Reduces IgG antibodies**

WHY IS THE PETUNIA STUDY BEING CONDUCTED?

The safety of **nipocalimab** has not been studied in pregnant people with gMG

Studies that evaluate **real-world safety** in pregnant people after a product is approved can be difficult, especially for rare diseases like gMG, because it can be hard to find enough people to take part in the research[8–10]

The **Pregnancy Enhanced Tracking with Neonatal and Infant Assessment (PETUNIA) study** was designed to learn what happens to pregnancies, mothers, and babies when nipocalimab is taken right before or during pregnancy, using a unique enhanced pharmacovigilance approach

HOW WILL THE STUDY BE PERFORMED?

PETUNIA is a **global, non-interventional, single-arm study** where researchers collect real-world postmarketing reports of **pregnancy exposure to nipocalimab** from the sponsor's global safety database from the time of first approval and over a period of **10 years**

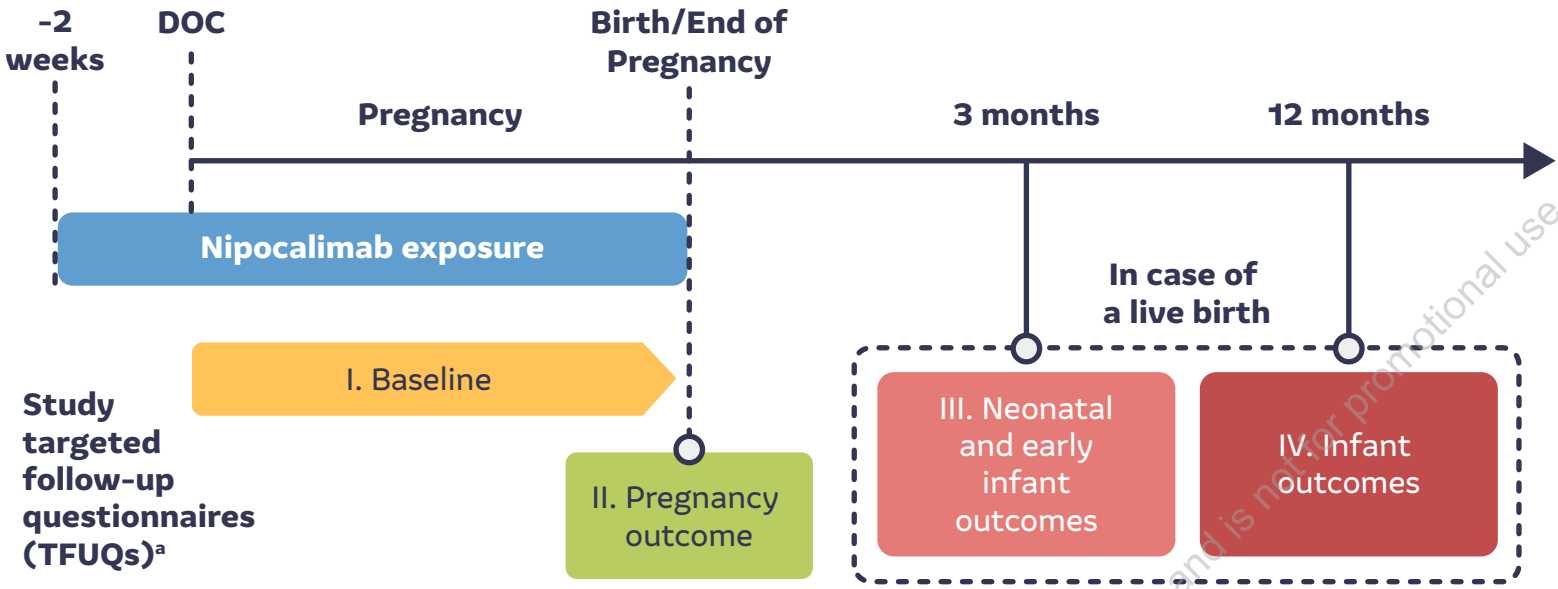
The study includes both **prospective reports** (reported while the pregnancy is ongoing and outcomes are not known) and **retrospective reports** (reported after outcomes are already known); the **primary analysis** will focus on the **prospective reports**

Researchers follow the **pregnancy** to the end and, when there is a **live birth**,

monitor the baby for up to 1 year

using **targeted follow-up questionnaires (TFUQs)**

completed by healthcare providers and/or pregnant people who report pregnancy exposure



TFUQ I

- Maternal information
- Current pregnancy information, including prenatal testing
- Exposure to medications and other substances during current pregnancy
- Maternal obstetric history
- Maternal history of MG
- Maternal medical history, including comorbidities
- Paternal history

TFUQ II

- Course of pregnancy (pregnancy and MG complications)
- MG disease activity during pregnancy
- Exposure to medications and other substances during current pregnancy
- Outcome of pregnancy

TFUQ III

- Infant status
- Infant medical history, including vaccination history
- Neonatal intensive care unit admission
- Outcomes including MCM[b] and serious infection
- Maternal status
- Maternal MG disease course and exposure to medication during lactation
- Postnatal growth deficiency
- Neurodevelopmental delay

TFUQ IV

- Infant status
- Infant medical history, including vaccination history
- Outcomes including MCM[b] and serious infection
- Maternal status
- Maternal MG disease course and exposure to medication during lactation
- Postnatal growth deficiency
- Neurodevelopmental delay

[a]Regardless of the timing of the initial report[c], all four questionnaires will be administered in order:
TFUQ I. Baseline → TFUQ II. Pregnancy outcome → TFUQ III. Neonatal and early infant outcomes → TFUQ IV. Infant outcomes.
[b]A birth defect that requires medical or surgical treatment, has a serious adverse effect on health and development, or has significant cosmetic impact.
[c]Pregnancy reports will be defined as prospective or retrospective based on the timing relative to the pregnancy and testing performed prior to the initial report.
DOC=date of conception, **MCM**=major congenital malformation, **MG**=myasthenia gravis, **TFUQ**=targeted follow-up questionnaire.

WHO WILL TAKE PART IN THE STUDY?

A pregnancy report can be included when:

- There is documented exposure to at least one dose of nipocalimab either within 2 weeks before the DOC or at any time during pregnancy in the postmarketing setting

A pregnancy report cannot be included when:

- Nipocalimab was stopped more than 2 weeks before the DOC
- Reported by someone other than the pregnant person or HCP and the pregnant person or HCP cannot be identified
- Insufficient information for reporter follow-up
- Nipocalimab exposure was in a clinical trial or other interventional study
- Paternal-only exposure to nipocalimab during the partner's pregnancy

It is expected that **at least 162 total pregnancies** will be included over a **10-year period** in countries where nipocalimab is approved and prescribed; of these, **at least 50 will be prospective cases** with known pregnancy outcomes

DOC=date of conception, **HCP**=healthcare provider.

HOW WILL RESEARCHERS ASSESS THE SAFETY OF NIPOCALIMAB?

To measure the safety of nipocalimab, researchers will evaluate predefined **primary** and **secondary endpoints** that are key health outcomes for the **pregnancy**, **mother**, and/or **baby**

Primary Endpoints

Pregnancy and neonatal outcomes

- Fetal growth restriction
- Small for gestational age
- Placental abruption
- Hypertensive disorders of pregnancy (i.e., pre-eclampsia; gestational hypertension; Hemolysis, Elevated Liver enzymes, and Low Platelets [HELLP] syndrome; and eclampsia)

Serious infections

- Serious infections in the neonate (0–27 days)
- Serious infections in the infant during the first year of life

Significant birth defects

- Non-chromosomal major congenital malformations[a]

Secondary Endpoints

Other outcomes for the pregnancy, mother, and baby

- Live birth
- Spontaneous abortion
- Stillbirth
- Preterm birth
- Intrapartum hemorrhage
- Postpartum hemorrhage
- Neonatal death
- Infant death

[a]A birth defect that requires medical or surgical treatment, has a serious adverse effect on health and development, or has significant cosmetic impact.

WHAT IMPACT WILL THE RESULTS OF THE PETUNIA STUDY HAVE?

The **PETUNIA study** is designed to collect **real-world safety** information about **maternal exposure to nipocalimab during pregnancy**

The knowledge gained from the study will support **clinical decision-making for pregnant people with gMG**

Glossary of technical terms

Date of conception (DOC)
The date when conception is estimated to have occurred, marking the beginning of pregnancy.

Enhanced pharmacovigilance
Improved safety monitoring that uses real-world reports plus structured follow-up questionnaires to gather complete and reliable safety information.

Hemolysis, Elevated Liver enzymes, and Low Platelets (HELLP) syndrome
A life-threatening pregnancy complication where red blood cells break down, liver function is impaired, and platelet levels fall, increasing the risk of organ damage and severe bleeding.

Immunoglobulin G (IgG) antibodies
A type of protein made by the immune system to fight infections. In generalized myasthenia gravis, these antibodies mistakenly attack the neuromuscular junction.

Major congenital malformation
A birth defect that requires medical or surgical treatment, has a serious adverse effect on health and development, or has a significant cosmetic impact.

Neonatal Fc receptor (FcRn)
A protein in the immune system that helps control how long IgG antibodies stay in the bloodstream.

Neonate
A newborn baby in the first 0–27 days of life.

Neuromuscular junction
The location where a nerve cell connects with a muscle cell and sends signals for the muscle to contract.

Non-chromosomal
Not caused by a problem in the number or structure of chromosomes.

Non-interventional, single-arm study
A study with only one group that observes what happens in real life and does not assign a control treatment.

Placental abruption
When the placenta separates too early from the uterus during pregnancy.

Postmarketing setting
The time period after a medicine has been approved and is being used in real-world care.

Prospective pregnancy report
A pregnancy exposure report made during the ongoing pregnancy and before the health outcome is known.

Retrospective pregnancy report
A pregnancy exposure report made after the health outcome is already known.

Spontaneous abortion
A natural, unexpected loss of pregnancy, often referred to as a miscarriage.

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AI disclosure

AI was used for partial preparation of this plain language summary with human input and oversight.