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

Neelam Goyal,[1] Christopher J Robinson,[2] Christiane Schneider-Gold,[3] Diana E Clements,[4] Marie Fitzgibbon,[5] Ibrahim Turkoz,[6] Lorraine S Gentner,[6] Toyin Adewole,[6] Lisa Schwartz,[5] Melanie H Jacobson[6]

[1]Stanford University School of Medicine, Stanford, CA, USA; [2]Novant Health East Cooper, Mount Pleasant, SC, USA; [3]St. Jozef Hospital, Ruhr-University of Bochum, Bochum, Germany; [4]Johnson & Johnson, Horsham, PA, USA; [5]Johnson & Johnson, Raritan, NJ, USA; [6]Johnson & Johnson, Titusville, NJ, USA

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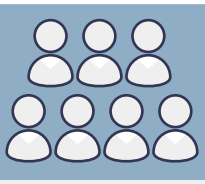
PETUNIA

WHAT IS MYASTHENIA GRAVIS (MG)?

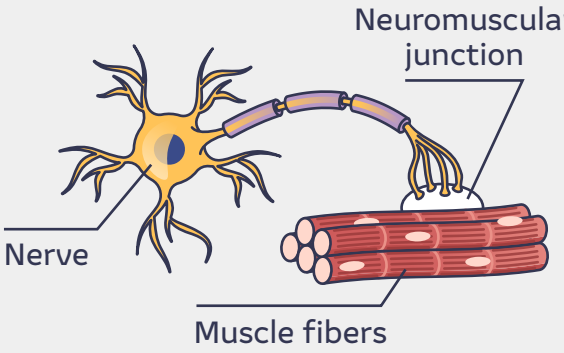
MG is a rare, chronic autoimmune disease that affects approximately **700,000** people worldwide[1]



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]

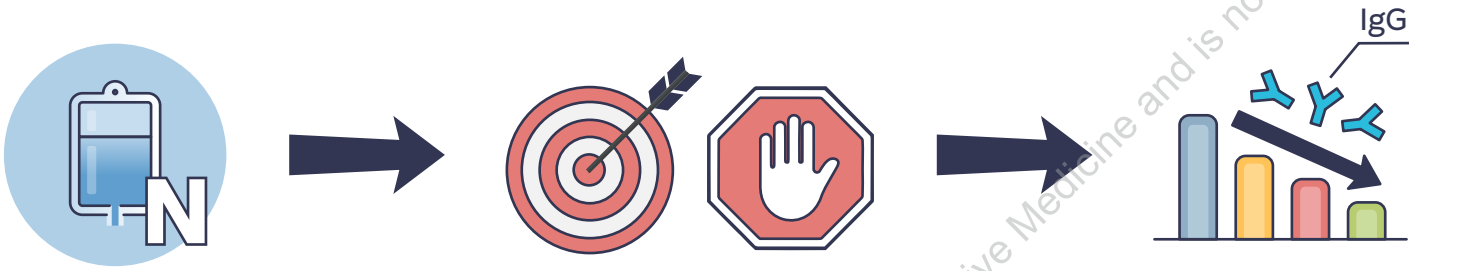
It happens when the body's **immune system mistakenly attacks** its own **muscles at the neuromuscular junction**, leading to **muscle weakness** that worsens with activity and improves with rest[1,2]



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**

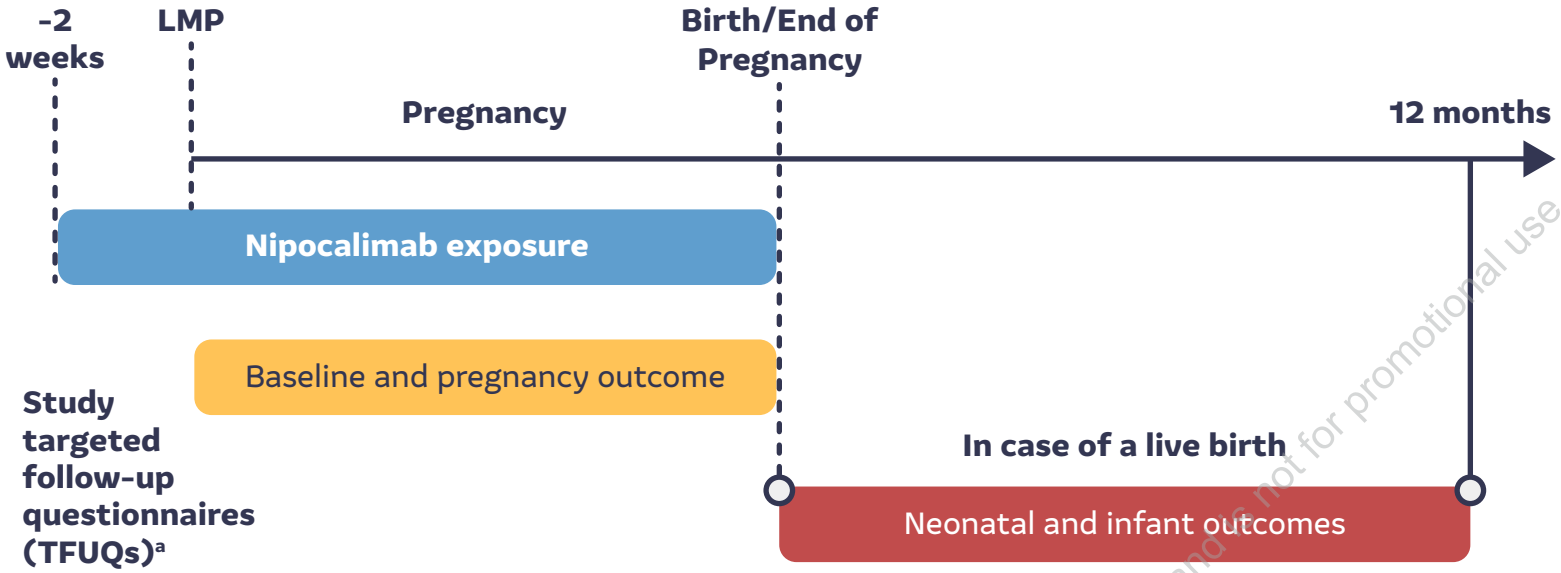
The study includes both **prospective reports** (reported while the pregnancy is ongoing and outcomes are not known) and **retrospective reports** (reported after outcomes are already known); the **primary analysis** will focus on the **prospective reports**

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



Baseline

- 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

Pregnancy outcome

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

Neonatal and infant outcomes

- 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

[a]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.

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

LMP=last menstrual period, **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 LMP 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 LMP
- 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

LMP=last menstrual period, **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

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.

Last menstrual period (LMP)
The first day of the last menstrual period, often used clinically to estimate when pregnancy began.

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.