

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 Jacobson⁶

¹Stanford University School of Medicine, Stanford, CA, USA; ²Novant Health East Cooper, Mount Pleasant, SC, USA;

³St. Jozef Hospital, Ruhr-University of Bochum, Bochum, Germany; ⁴Johnson & Johnson, Horsham, PA, USA;

⁵Johnson & Johnson, Raritan, NJ, USA; ⁶Johnson & Johnson, Titusville, NJ, USA

This plain language summary infographic was prepared from an encore poster presented at the 2026 American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting (Orland, FL, USA; September 29 October 2, 2026).



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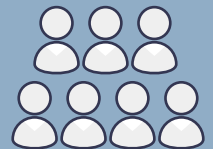


WHAT IS MYASTHENIA GRAVIS (MG)?



MG is a rare, chronic autoimmune disease that affects approximately

700,000
people worldwide¹

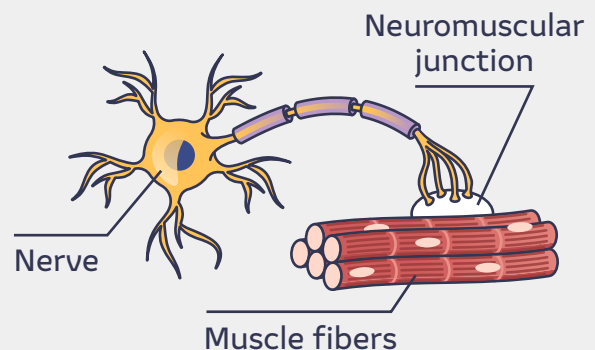


Symptoms typically start as **eye-related** (i.e., droopy eyelids, double vision), but the disease often progresses to **generalized MG (gMG)** where **other muscle groups** across the body are affected, such as those used for **talking, chewing**, and even **breathing**^{1,3}

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 research⁸⁻¹⁰



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**,

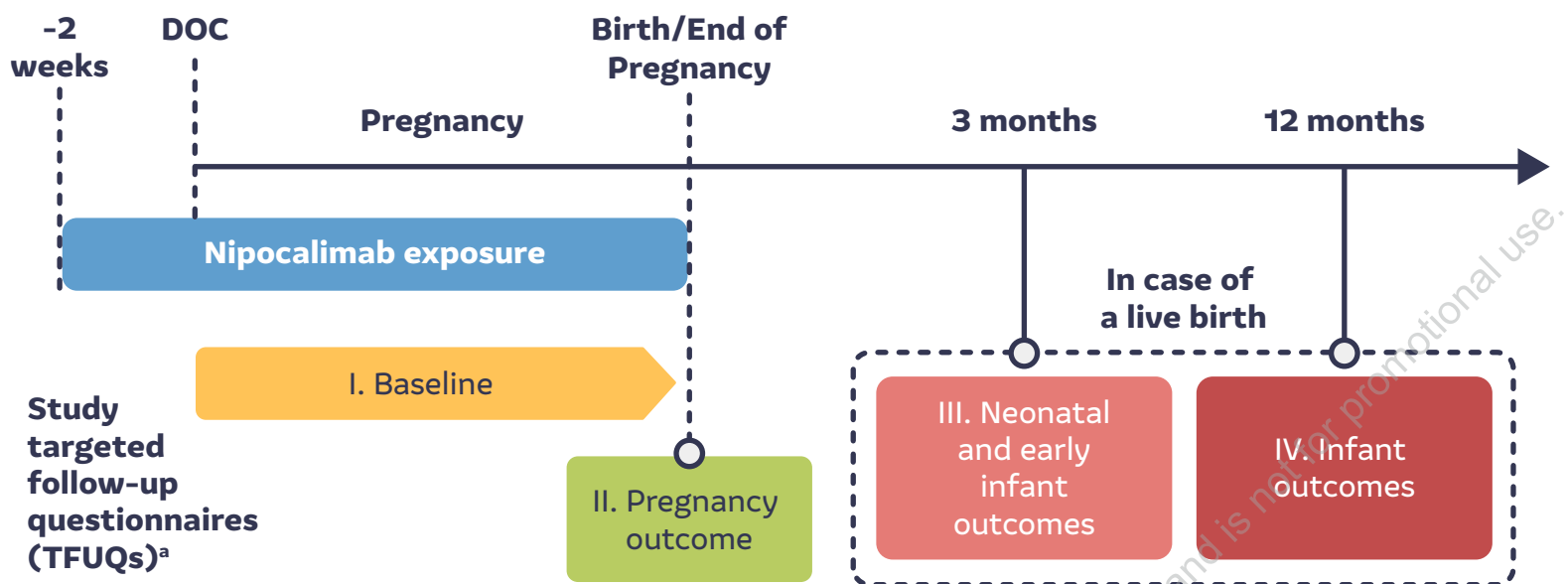


monitor the baby for up to 1 year



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

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



TFUQ I	TFUQ II	TFUQ III	TFUQ IV
◦ 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	◦ Course of pregnancy (pregnancy and MG complications) ◦ MG disease activity during pregnancy ◦ Exposure to medications and other substances during current pregnancy ◦ Outcome of pregnancy	◦ 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	◦ 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

^aRegardless 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.

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

^cPregnancy 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

^aA 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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Funding

This study is sponsored by Johnson & Johnson.

Acknowledgments

Medical writing and editorial support were provided by Margaret Van Horn, PhD, CMPP (Johnson & Johnson) and Twist Medical under the direction of the authors in accordance with Good Publication Practice guidelines (*Ann Intern Med*. 2022;175:1298–304) and were funded by Johnson & Johnson.

AI disclosure

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