

Future Neurology

ISSN: 1479-6708 (Print) 1748-6971 (Online) Journal homepage: www.tandfonline.com/journals/ifnl20

Vivacity-MG3 study comparing nipocalimab versus placebo treatment in patients with generalized myasthenia gravis: A Plain Language Summary of Publication

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To cite this article: Carlo Antozzi, Tuan Vu, Sindhu Ramchandren, Richard J Nowak, Constantine Farmakidis, Vera Bril, Jan De Bleecker, Huan Yang, Eduard Minks, Jin-Sung Park, Mariusz Grudniak, Marek Smilowski, Teresa Sevilla, Sarah Hoffmann, Kumaraswamy Sivakumar, Yasushi Suzuki, Eriene Youssef, Panna Sanga, Dan Huang, Yaowei Zhu, John J Sheehan, Hong Sun & The Vivacity-MG3 Study Group (2026) Vivacity-MG3 study comparing nipocalimab versus placebo treatment in patients with generalized myasthenia gravis: A Plain Language Summary of Publication, Future Neurology, 21:1, 2647797, DOI: 10.1080/14796708.2026.2647797

To link to this article: https://doi.org/10.1080/14796708.2026.2647797

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Plain Language Summary of Publication

Future NEUROLOGY

Vivacity-MG3 study comparing nipocalimab versus placebo treatment in patients with generalized myasthenia gravis: a plain language summary of publication

Carlo Antozzi[a], Tuan Vu[b], Sindhu Ramchandren[c], Richard J Nowak[d], Constantine Farmakidis[e], Vera Bril[f], Jan De Bleecker[g], Huan Yang[h], Eduard Minks[i], Jin-Sung Park[j], Mariusz Grudniak[k], Marek Smilowski[l], Teresa Sevilla[m], Sarah Hoffmann[n], Kumaraswamy Sivakumar[o], Yasushi Suzuki[p], Eriene Youssef[c], Panna Sanga[c], Dan Huang[q], Yaowei Zhu[c], John J Sheehan[r], Hong Sun[c*], The Vivacity-MG3 Study Group

Author affiliations can be found at the end of this article.

First draft submitted: 16 January 2026; Accepted for publication: 11 March 2026

Where can I find the original article on which this summary is based?

This summary is based on the original article, titled 'Safety and efficacy of nipocalimab in adults with generalized myasthenia gravis (Vivacity-MG3): a phase 3, randomized, double-blind, placebo-controlled study', which was originally published in *Lancet Neurology*. You can access it for a fee at: https://www.thelancet.com/journals/laneur/article/PIIS1474-4422(24)00498-8/abstract

Summary

How to say (download PDF and double click sound icon to play sound)…

- **Myasthenia gravis:** mai-uhs-thee-nee-uh gra-vuhs
- **Nipocalimab:** Ni-po-KA-li-mab
- **Placebo:** Pluh-SEE-boh

What is this summary about?

Generalized myasthenia gravis (gMG) is a long-term **autoimmune** disease where the immune system attacks the nerve-muscle junction causing muscle weakness. This summary describes results from Vivacity-MG3, a 24 week Phase-3 **randomized controlled trial**, that investigated whether nipocalimab is safe and improves symptoms in patients with gMG who did not get sufficient symptom relief with **standard-of-care treatments**. Participants could have **autoantibodies** for acetylcholine receptor [AChR], muscle-specific tyrosine kinase receptor-related protein [MuSK], or low-density lipoprotein receptor-related protein-4 [LRP4]. These autoantibodies may lead to the development of gMG.

What were the results?

The study included 196 patients, who were receiving standard-of-care treatments for gMG. In addition to standard-of-care treatments, 98 patients received nipocalimab, while the remaining 98 received **placebo**. Over 24 weeks, nipocalimab-treated patients showed greater improvements in gMG symptoms compared to placebo. The most common side effects were COVID-19-related side effects, headache, muscle spasms, **myasthenia gravis worsening**, and **peripheral edema**.

What do the results mean?

In patients with gMG who are positive for **antibodies** to AChR, MuSK, or LRP4, nipocalimab added to standard-of-care treatments was more effective in treating gMG symptoms over 24 weeks of treatment than placebo added to standard-of-care treatments, with a tolerable **safety profile**. The **efficacy** and safety of nipocalimab when used for longer than 24 weeks is being evaluated in an ongoing **open-label extension** of this study.

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Autoimmune: A health condition that happens when the body's immune system attacks the human body instead of defending it.

Randomized controlled trial: A type of study where participants are divided by chance into different groups where one group receives the active treatment being tested and the other group receives placebo. In some trials, such as this one, the active treatment or placebo is given in addition to standard-of-care treatments currently used for the disease.

Standard-of-care treatments: Current treatments approved and commonly used to treat a disease. It included acetylcholinesterase inhibitors (eg. pyridostigmine), corticosteroids, and non-steroid immunosuppressants (eg. azathioprine).

Autoantibodies: Are formed when the immune system is not working properly. The body creates a specific kind of antibody (called an autoantibody) that mistakenly attack the body's own healthy cells and tissues. Autoantibodies are harmful and may lead to development of an autoimmune disease such as gMG. In Myasthenia gravis, the most common autoantibodies are IgG autoantibodies against AChR, MuSK, and LRP4.

Placebo: A treatment that looks just like the real study medicine but does not contain any active medicine. It is used in research to help show whether the real study medicine works better than no treatment.

Myasthenia gravis worsening: Some patients with gMG experience increase in muscle weakness, even while they are receiving treatment, due to the fluctuating nature of the disease and individual differences in treatment response.

Peripheral edema: Swelling in areas of the body, most commonly the feet, ankles, or legs or hands. It happens when excess fluid builds up in the tissues and may cause the affected area to look puffy or feel tight.

Antibodies: Antibodies or Immunoglobulins (Ig) are produced by the body to fight against germs. There are 5 types, each having a different role in the immune response: IgG, IgM, IgA, IgD and IgE.

Safety profile: A summary of how safe a treatment is, based on the types and frequencies of side effects seen in people who received it during the study.

Efficacy: The ability to produce the desired or intended results, for example, with a medication.

Open-label extension: A follow-up to a clinical trial where both the researchers and participants know that everyone is receiving the active treatment. This allows researchers to gather long-term safety and effectiveness data on the active treatment being tested.

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What is the purpose of this plain language summary?

To provide an overview of how nipocalimab works to lower levels of harmful autoantibodies and manages the symptoms of gMG.

To present the key results from a large phase 3 clinical trial (Vivacity-MG3) that assessed the efficacy and safety of nipocalimab versus placebo in patients with gMG, who were still experiencing symptoms despite standard-of-care treatments.

To understand how the results of this study may differ from those of other studies, thereby informing clinicians' interpretation of evidence for making treatment decisions.

Nipocalimab is used to treat the condition under study that is/are discussed in this summary. Approval varies by country; please check with your local provider for more details.

The results of this study may differ from those of other studies. Health professionals should make treatment decisions based on all available evidence not on the results of a single study.

Who should read this article?

This article is intended for people who are new in the field of gMG and wish to understand how nipocalimab may help patients with gMG.

It may also be helpful for a non-specialist audience (including but not limited to general practitioners, non-specialist healthcare providers, nurses, physician assistants, pharmacists, research scientists, decision-makers, and health care analysts) who may want to know about new treatments for gMG.

Who sponsored this study?

This study was **sponsored** by Johnson & Johnson.

Sponsor: In a clinical trial, the sponsor is the company or organization that takes responsibility for initiating, managing, and financing the trial.

The sponsor oversees the trial, ensures it is conducted ethically and scientifically, and analyzes and reports the data collected from the trial.

What is gMG?

In gMG, harmful immunoglobulin G (IgG) antibodies called autoantibodies attack certain proteins involved in communication between the nerve and the muscle; disrupting these proteins can cause symptoms of gMG.

Under normal conditions, the brain sends signals to muscles through nerves. At the point where a nerve communicates with a muscle, a chemical called acetylcholine (ACh) is released. This chemical binds to receptors on the muscle — such as AChR — allowing the muscle to generate an electrical signal and contract.

In most patients with gMG (about 85%), autoantibodies attack a protein called the acetylcholine receptor (**AChR**). In some patients (about 8%), they attack a different protein called muscle-specific tyrosine kinase receptor (**MuSK**) and in 1–2%, they attack a protein called low-density lipoprotein receptor-related protein 4 (**LRP4**). In the small remainder of patients with gMG (5%), these autoantibodies are not detected, but patients still experience symptoms of gMG.

In gMG, over time, autoantibodies can attack and destroy the AChR on muscle cells. As a result, the muscles cannot generate an electric signal and become weak. Affected muscles can include the face, neck, arms, and legs, and consequently, patients with gMG may have symptoms like drooping eyelids, double vision, shortness of breath, difficulty smiling, slurred speech, and trouble chewing or swallowing. These symptoms can fluctuate, meaning they can increase (worsen) with activity or decrease (improve) with rest.

AChR: A protein receptor on the surface of muscle cells that acts like a tiny doorway. When a specific chemical called acetylcholine (ACh) binds to it, it opens up and allows other chemicals to flow into and out of the muscle cell, creating an electric signal in the muscle, which helps in muscle movement.

MuSK and **LRP4:** Are proteins that help organize AChR on the surface of muscle cells.

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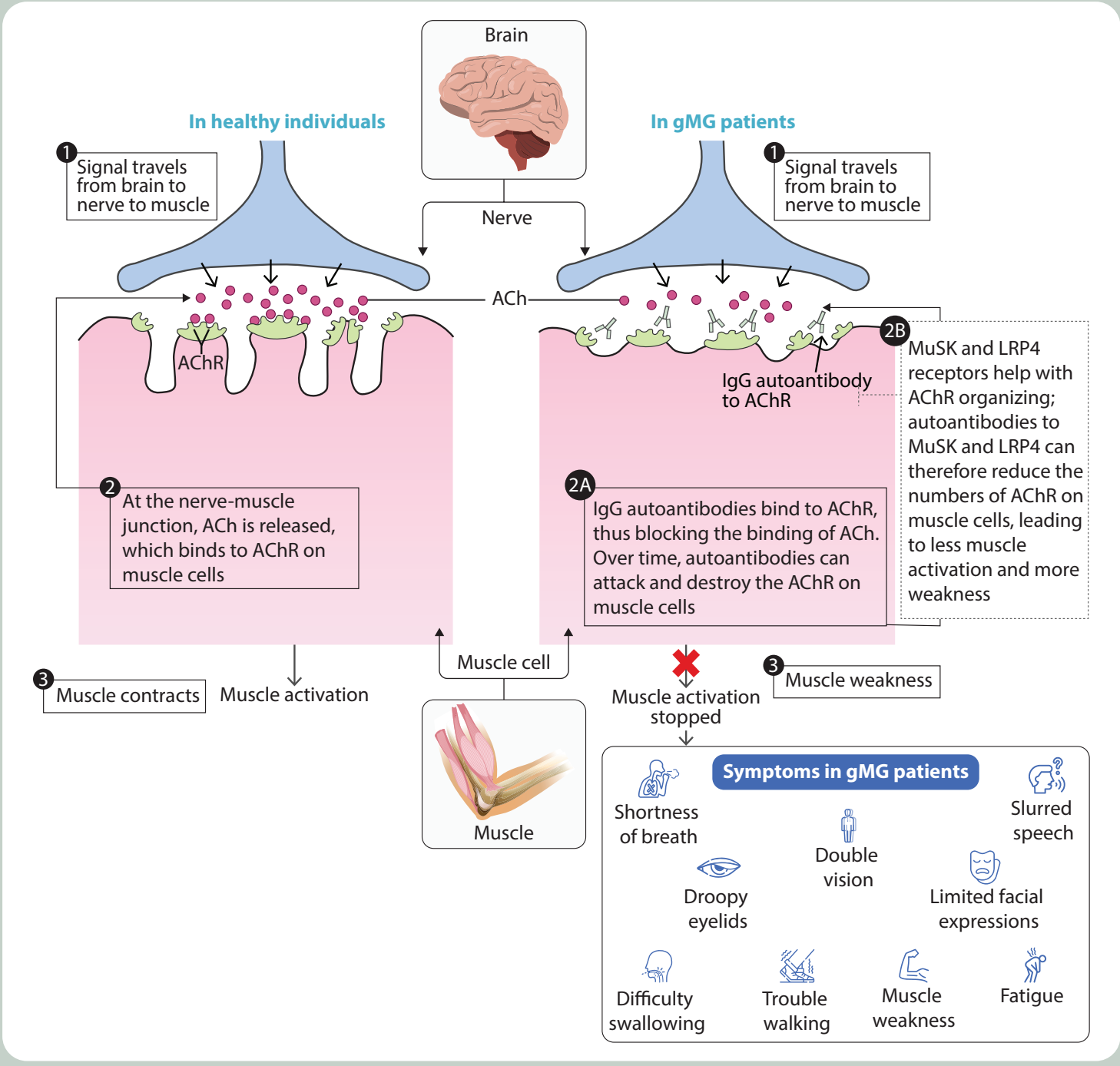


What is nipocalimab?

Nipocalimab is a medication designed to lower IgG antibodies, including the harmful IgG autoantibodies that cause gMG symptoms, by blocking a protein receptor, called the FcRn receptor.

How can nipocalimab help patients with gMG?

The immune system produces antibodies to defend the body against germs and other foreign substances. To keep the levels of antibodies high in the blood, the body has a natural process that preserves IgG antibodies and returns them to the bloodstream.

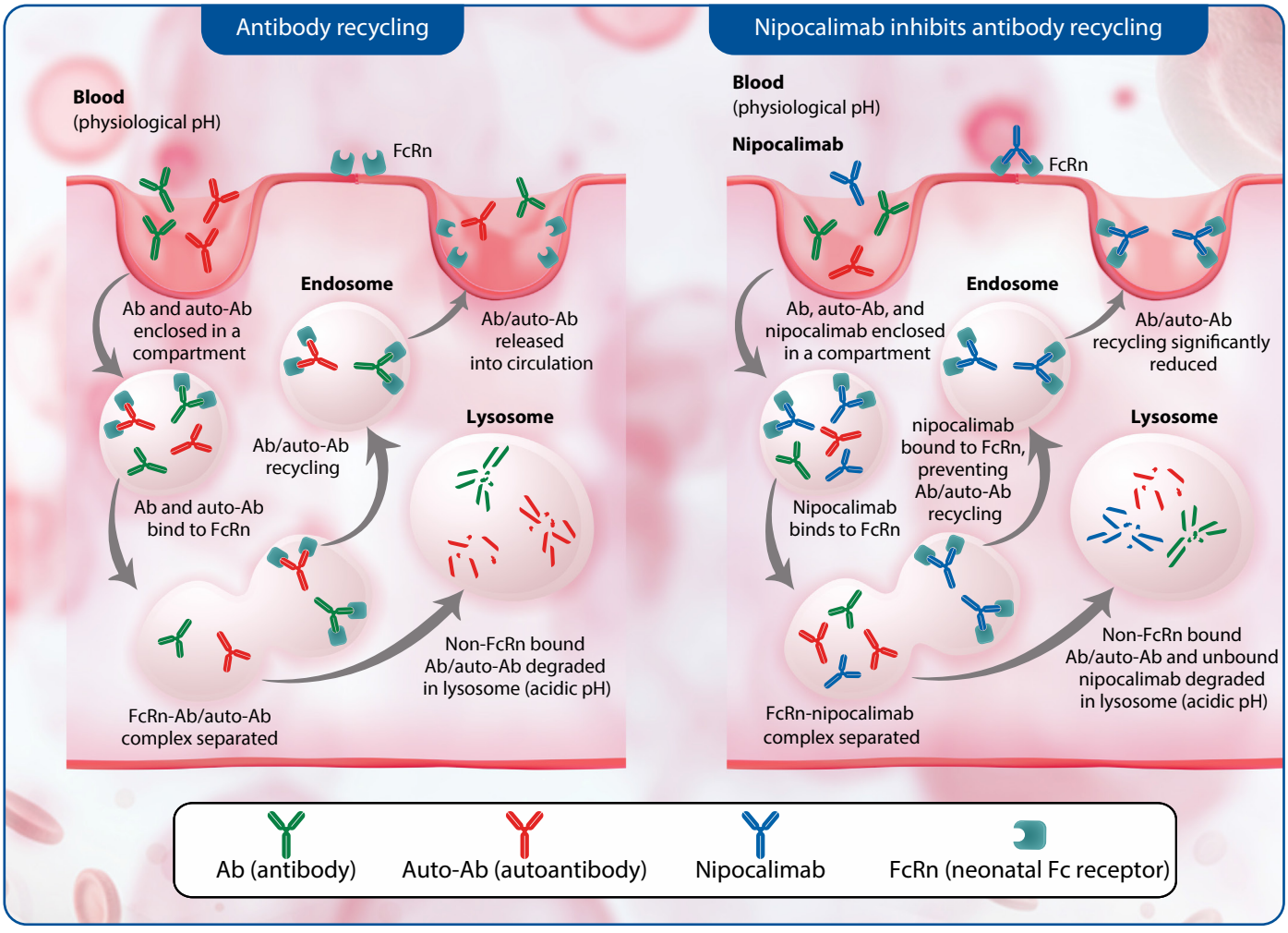
Neonatal Fc receptor: Is a protein in our body that helps antibodies stay in the bloodstream for a longer time.

This process of recycling IgG antibodies is mediated by the **neonatal Fc receptor (FcRn)**, a protein expressed on many cell types. FcRn binds IgG antibodies inside cells and restores them to the circulation, allowing IgG antibodies to remain in the body for longer periods.

In patients with gMG, the immune system produces harmful IgG autoantibodies that mistakenly attack the body's own proteins. FcRn also recycles these autoantibodies, which prolongs their presence in the circulation and contributes to ongoing disease symptoms.

Nipocalimab works by blocking FcRn. By preventing FcRn from binding IgG antibodies inside cells and therefore preventing the return of these antibodies and autoantibodies to the bloodstream, nipocalimab leads to a reduction in overall IgG levels, including harmful autoantibodies. This decrease in harmful autoantibodies helps reduce the symptoms of gMG.

Events that take place within cells (endothelial cells) lining blood vessels



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Why was the study done?

This study was conducted:

- To evaluate if nipocalimab can improve symptoms of gMG to a greater extent than placebo, through 24 weeks of treatment, when each is added to standard-of-care treatments.
- To understand what side effects occurred in patients who took nipocalimab or placebo.

How was the study conducted?

The Vivacity-MG3 study was a **pivotal phase 3 clinical study** and it involved the following:

- Randomized, placebo-controlled, double-blind study: A total of 199 patients with gMG were enrolled for study, of whom 196 (98 in each treatment group) were randomized to receive either nipocalimab or placebo (a treatment with no active medicine), in addition to their usual standard-of-care treatments for gMG. Neither the patients nor their doctors knew who was receiving nipocalimab and who was receiving placebo until the study was completed ('double blind'). This part of the study lasted 24 weeks (6 months).
- Multicenter: The study was carried out at 81 study centers (hospitals or clinics) in 17 countries across Asia-Pacific, Europe, and North America.
- Dosing: In addition to their standard-of-care treatments for gMG, patients in placebo group received placebo (a loading dose followed by a maintenance dose every 2 weeks) and patients in nipocalimab group received nipocalimab (a **loading dose** of 30 mg/kg followed by a **maintenance dose** of 15 **mg/kg** every 2 weeks) through an intravenous (IV) infusion for 24 weeks.

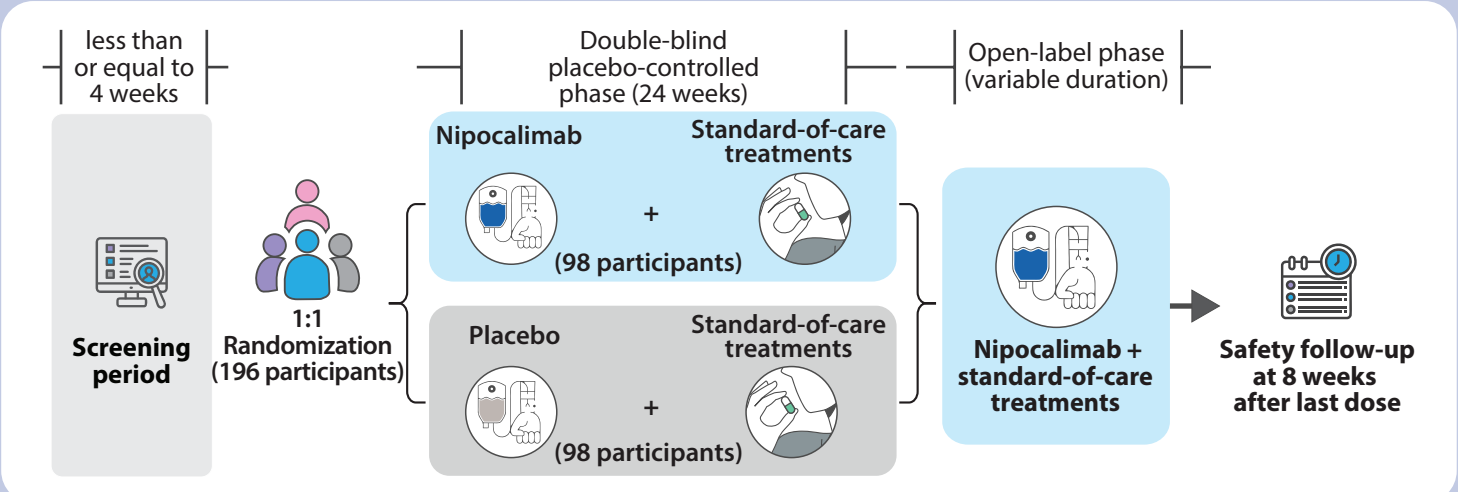
Pivotal phase 3 study: A crucial part of clinical research that aims to confirm the safety and effectiveness of a new treatment, often a drug, for a specific condition. These studies typically involve large numbers of participants and are designed to provide the evidence needed for regulatory approval by health authorities like the Food and Drug Administration (FDA) for wider use.

Loading dose: This is a larger initial dose of medicine usually given at the beginning of a treatment to rapidly achieve a high enough level of medicine in the blood so that the effect of the medicine can be reached faster.

Maintenance dose: These are regular doses given to maintain a certain level of medicine in the blood and therefore continue the effects of medication.

mg/kg dosing: This means the dose is calculated per the weight of the patient. For example, a patient who weighs 60 kg in this study would get a maintenance dose of 15 mg/kg x 60 kg = 900 mg.

If a patient's symptoms got worse, they were provided urgent rescue treatment. Rescue treatment could be intravenous IgG or plasma exchange. Intravenous IgG is a treatment given through a vein that provides healthy antibodies to help quickly reduce the harmful immune attack causing MG symptoms. Plasma exchange is a procedure that removes the patient's plasma and replaces it with healthy fluid to quickly lower harmful antibodies that worsen MG. After 24 weeks, patients could choose to continue in an open-label extension (longer follow-up) phase of the study. Patients who had received rescue treatment were also allowed to move into the open-label extension phase.



Who took part in this gMG study?

Inclusion criteria:

- Adults (18 years or older) with gMG.
- Diagnosis of gMG with a MGFA Clinical Classification Class II a/b, III a/b, or IVa/b at screening.
- MG-ADL score of 6 or higher at the beginning of the study.
- Patients with insufficient control of symptoms despite stable standard-of-care treatments for gMG.

Exclusion criteria:

- Confirmed/suspected clinical immunodeficiency syndrome not related to treatment for gMG taken, or family history of congenital/hereditary immunodeficiency.
- Presence of MGFA Class I disease or MG crisis (MGFA Class V) at screening or history of MG crisis within 1 month of screening, or fixed weakness (and/or 'burnt out' MG).
- Thymectomy within 12 months prior to screening, or thymectomy is planned during the study.
- Known allergies, hypersensitivity, or intolerance to nipocalimab or its excipients.
- Myocardial infarction, unstable ischemic heart disease, or stroke within 12 weeks of screening.
- Received other treatments such as rituximab, intravenous immunoglobulins, shortly before the first dose of study treatment.

Women of childbearing potential could not be pregnant at the start of the study, and were required to practice a highly effective form of birth control during the study.

What does MGFA class for gMG mean?

The Myasthenia Gravis Foundation of America (MGFA) classification is a system used to categorize the severity and presentation of gMG:

- Class I: Any ocular (related to eyes such as double vision, eyelid droop) MG. All other muscle strength is normal.
- Class IIa: Mild weakness, predominantly affects limb or axial muscles (axial muscles are muscles supporting and moving the skull, spine, and rib cage).
- Class IIb: Mild weakness, predominantly affects bulbar (speech and swallowing) or respiratory (breathing) muscles.
- Class IIIa: Moderate weakness, predominantly affects limb or axial muscles.
- Class IIIb: Moderate weakness, predominant bulbar or respiratory muscle involvement.
- Class IVa: Severe weakness, predominantly affects limb or axial muscle involvement.
- Class IVb: Severe weakness, predominantly affects bulbar or respiratory muscles.
- Class V: Defined as intubation, with or without mechanical ventilation, except when employed during routine postoperative management.

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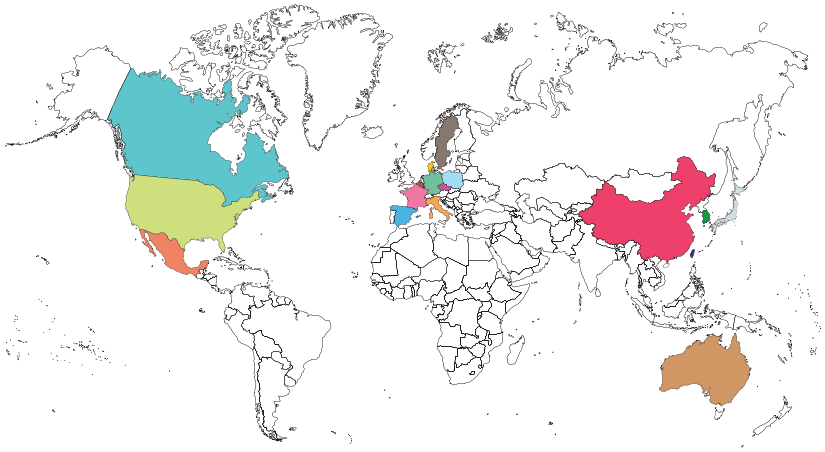
From where were the patients recruited?

The study was carried out at 81 sites in 17 countries/regions:



What were the overall patient characteristics, for those included in the study?

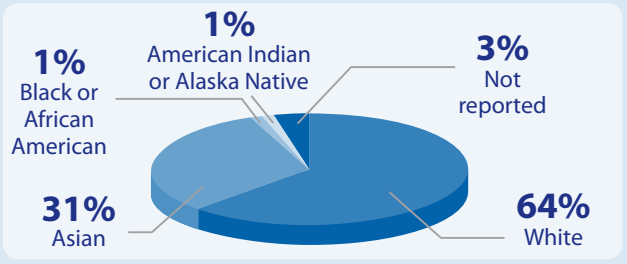
Demographic characteristics are presented based on efficacy analysis set population: nipocalimab + standard-of-care treatments (77 participants) and placebo + standard-of-care treatments (76 participants).

The baseline demographic and clinical characteristics of the patients closely reflected those observed in the broader gMG population.

Nipocalimab + standard-of-care treatments

Age **52.5** years on average

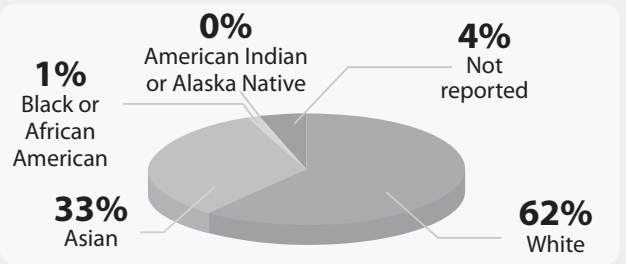
65% Female **35%** Male



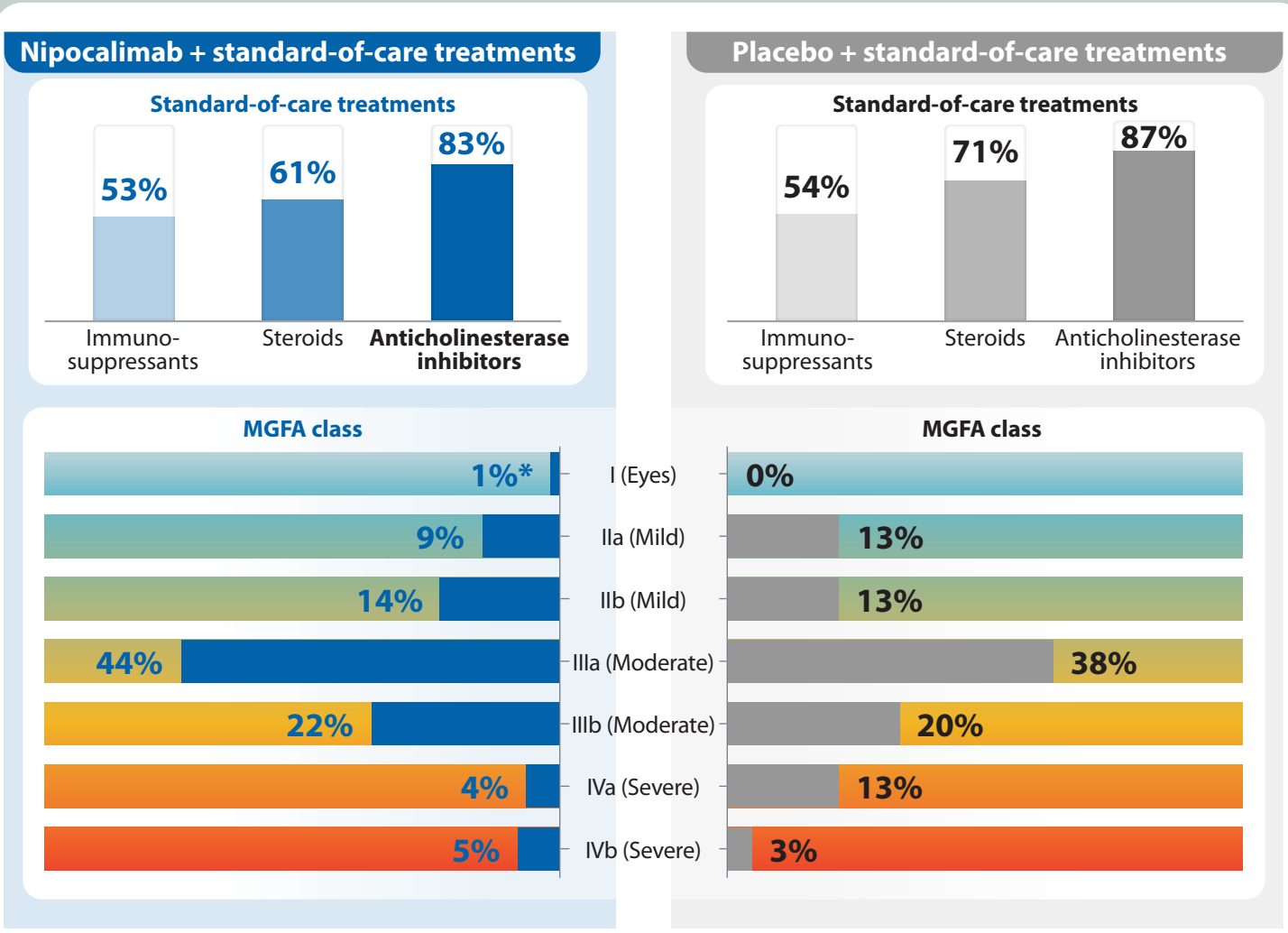
Placebo + standard-of-care treatments

Age **52.3** years on average

55% Female **45%** Male



What was the treatment and disease status of the patients at the start of the study?



*Patient had MGFA class IIa at screening and MG-ADL of 8 at both screening and baseline.

Anticholinesterase inhibitors: Are medicines that help improve muscle strength in people with gMG by keeping more of the natural messenger (acetylcholine) available.

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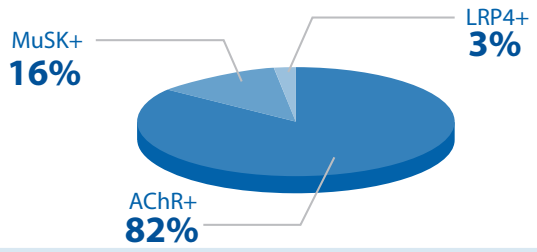
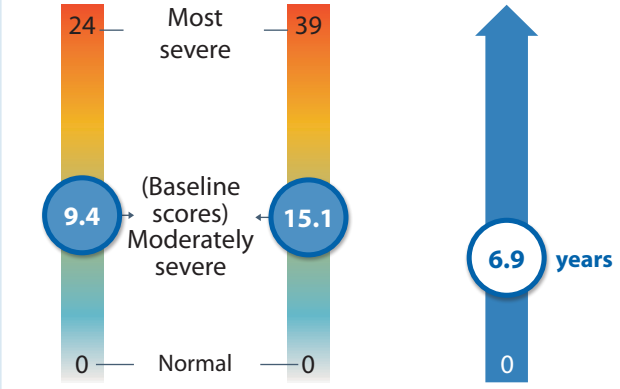
What was the disease status of the patients at the start of the study?

Nipocalimab + standard-of-care treatments

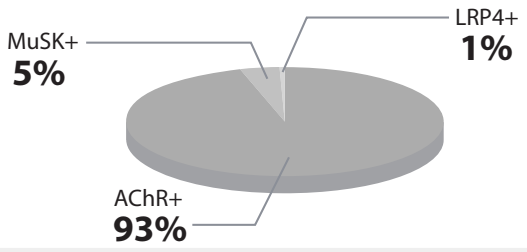
Antibody-positive status at screening

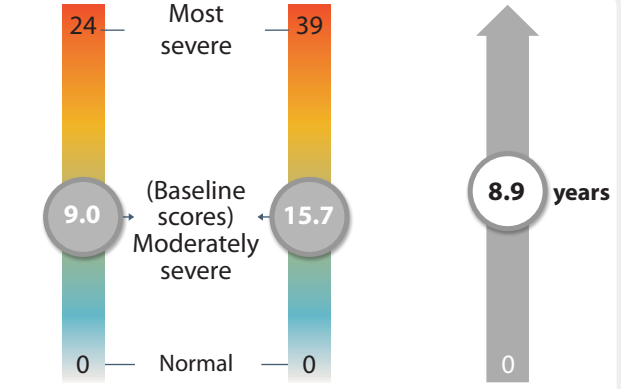




Placebo + standard-of-care treatments

Antibody-positive status at screening





Mean (SD): The mean is the average value in a group. It is calculated by adding up all the values and dividing by the number of people. The standard deviation (SD) shows how much the values vary from the average. A small SD means most values are close to the average, while a large SD means the values are more spread out. Example: An age of 60 years (SD 8) means the average age was 60 years, and most people were within about 8 years older or younger than that.

MG-ADL scale: This scale is a simple questionnaire completed by a doctor based on a patient's recall of symptoms over the previous 7 days to see how much gMG is affecting patient's daily life activities, such as talking, swallowing, moving arm, etc. Doctors use this scale to measure the severity of individual MG symptoms using a score of 0 (normal) to 3 (severely affected). The items can be added up to derive a total score ranging from 0 to 24. The higher the score, the more severe are the symptoms. A comparison of the scores over time helps doctors to understand if a treatment is helping to improve symptoms.

QMG scale: This is a scale that allows doctors to measure the severity of gMG symptoms in the patient. It measures muscle weakness in various areas, including eyes, face, speech and swallowing, gross motor, axial, and breathing functions. The total score ranges from 0 to 39, with higher scores indicating greater muscle weakness. A comparison of the scores over time helps doctors understand if a treatment is helping to improve muscle strength.

What did the study assess?

Safety: was assessed in all participants in the study (with or without autoantibodies) who received at least one partial or complete dose of study treatment (nipocalimab or placebo).

Efficacy: was measured mainly in the study participants who had MG-related autoantibodies and received at least one partial or complete dose of study treatment (nipocalimab or placebo).

Name of the assessment	What does it measure?	Score range	Making sense of this information
 **Myasthenia Gravis-Activities of Daily Living total score (MG-ADL)**	Measures how gMG affects the ability to do everyday activities (e.g. talking, swallowing)	0 to 24 (scored based on patient recall)	Decrease in score from study **baseline** means improvement in the ability to do everyday activities
 **Quantitative Myasthenia Gravis total score (QMG)**	Measures the severity of gMG symptoms (e.g. swallowing, breathing, double vision)	0 to 39 (scored based on assessment of muscle function by a doctor)	Decrease in score from study baseline means a reduction in the severity of the symptoms
 **Adverse events (AEs)**	Side effects experienced by patient during the study	-	This helps doctors and patients understand what side effects can occur
 **Pharmacodynamic (PD) assessments**	PD assessments in this study measure the effect of medicine (nipocalimab) on the levels of antibodies and autoantibodies	-	Monitoring levels of antibodies and autoantibodies helps to understand the safety and effectiveness of treatment being tested

Baseline: The initial measurements (eg. MG-ADL score) or conditions of disease before starting the study treatment.

Adverse events: These are new or worsening health issues that appear during or soon after a medical treatment.

Pharmacodynamics: Studying what medicine does to your body and how. Pharmacodynamics explores the biochemical, physiological, and molecular effects of medicine on the body including their mechanism of action.

What were the endpoints of the study and how they were assessed?

These assessments were divided into various endpoints: **primary (main) endpoint**, **key secondary endpoints**, **other secondary endpoints**, pharmacodynamic endpoints, and safety endpoints.

Primary and key secondary endpoints were analyzed in hierarchical order.

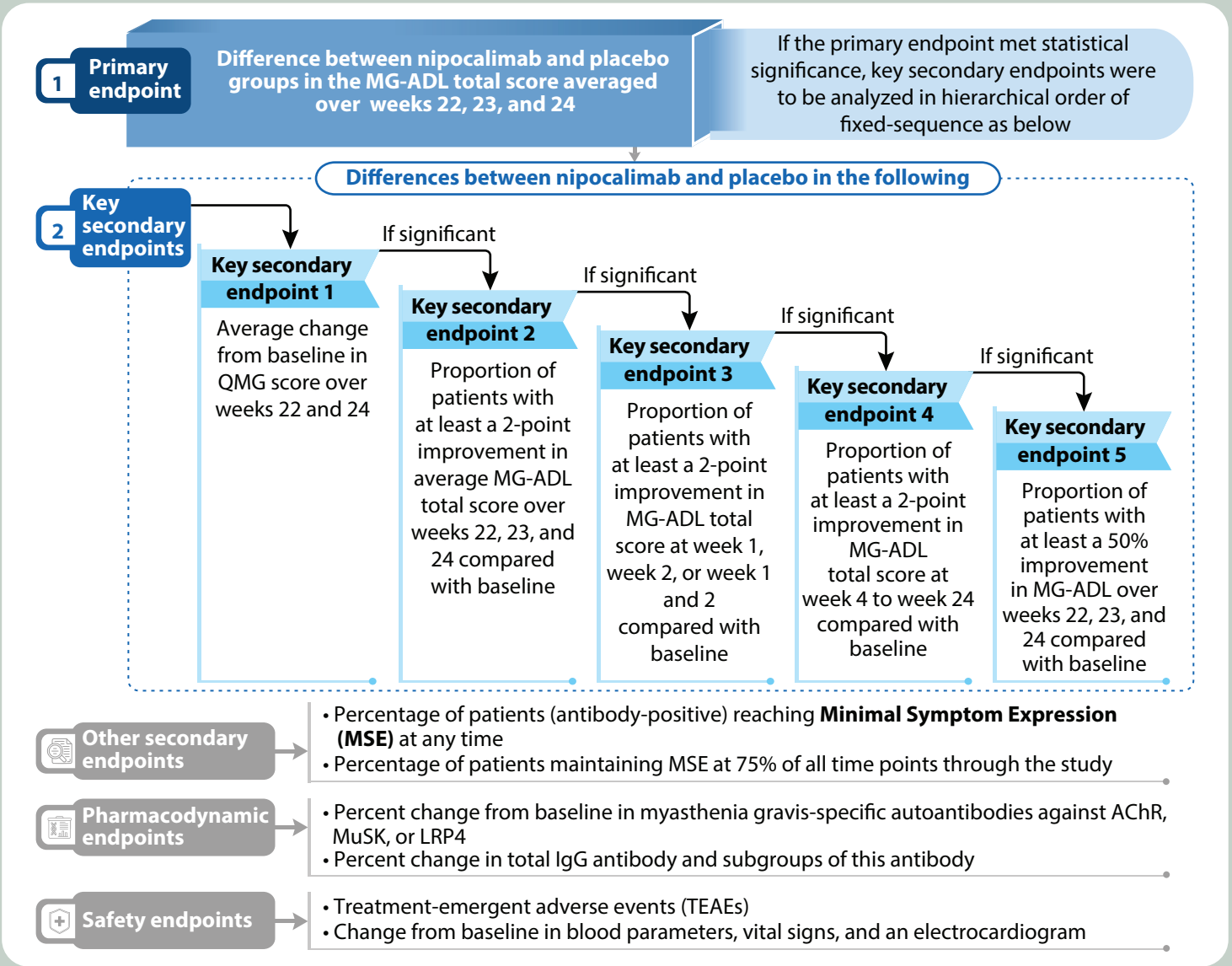
Hierarchical analysis with fixed-sequence approach: In this approach, the endpoints are arranged in a logical sequence, with the most important (primary endpoint) at the top and others below. Each endpoint is tested only if a significant difference between nipocalimab and placebo is identified through the previous endpoint. This approach helps ensure that the conclusions are not due to chance.

Primary endpoint: The outcome the researchers thought was the most important outcome for a study to assess. It is the key variable that determines whether the study is considered successful.

Key secondary endpoint: An additional outcome beyond the primary endpoint measured during the study. They are specific, pre-defined outcomes that, if **statistically significant**, can provide stronger evidence of a treatment's clinical benefit, similar to a primary endpoint.

Other secondary endpoints: An additional outcome of interest that may provide supportive information about a treatment's effect on the primary endpoint or demonstrate additional effects on the disease or condition.

Minimal Symptom Expression (MSE): Reduction of MG-ADL score down to 0 or 1. It indicates symptoms are minimal and the patient can do everyday activities normally/with minimal difficulty.

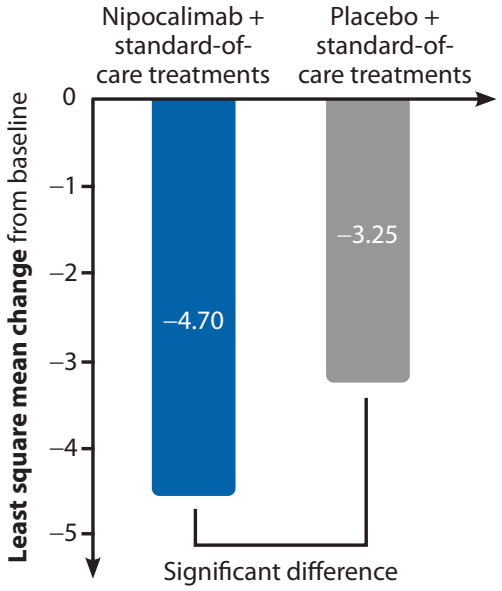


What were the overall results of the study?

Results for the primary endpoint (improvement in MG-ADL)

Nipocalimab showed **statistically significant** improvement from baseline in the MG-ADL scores over weeks 22, 23, and 24, compared to the placebo group.

Improvement in MG-ADL score



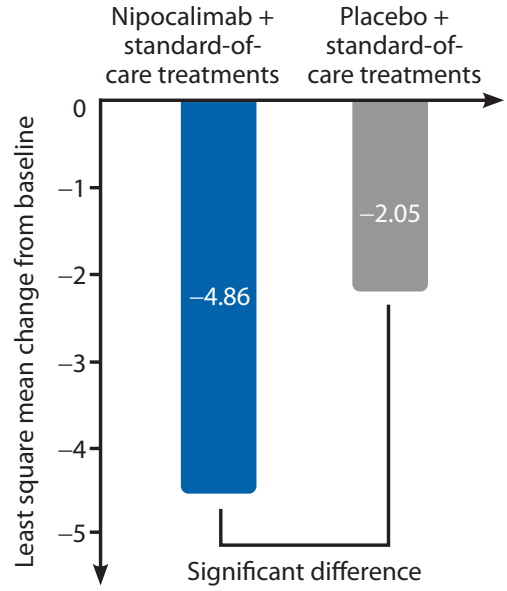
Making sense of this information

Longer bars (blue color) show greater symptom improvement with nipocalimab than placebo. This means that patients who received nipocalimab experienced greater relief from their gMG symptoms compared to those who received placebo.

Results for key secondary endpoint 1 (improvement in QMG)

Patients treated with nipocalimab showed greater improvement from baseline in the QMG scores over weeks 22 and 24 compared to those who received placebo.

Improvement in QMG score



Making sense of this information

Longer bars (blue color) show greater improvement with nipocalimab than placebo.

Least squares mean change: Is the average change from the start of the study, calculated in a way that fairly compares groups by adjusting for differences between patients such as patient characteristics or other factors considered in the analysis.

What does statistical significance determine in the context of this study?

Statistical significance helps determine whether the results seen (in this case, improvements) are by chance or due to effect of the medicine (in this case, nipocalimab). The difference between placebo and nipocalimab through 24 weeks of treatment duration was statistically significant in most assessments. This means the researchers can confidently conclude the differences observed were due to nipocalimab and not by chance.

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Results for key secondary endpoints 2 to 5 (2-point improvement in MG-ADL)

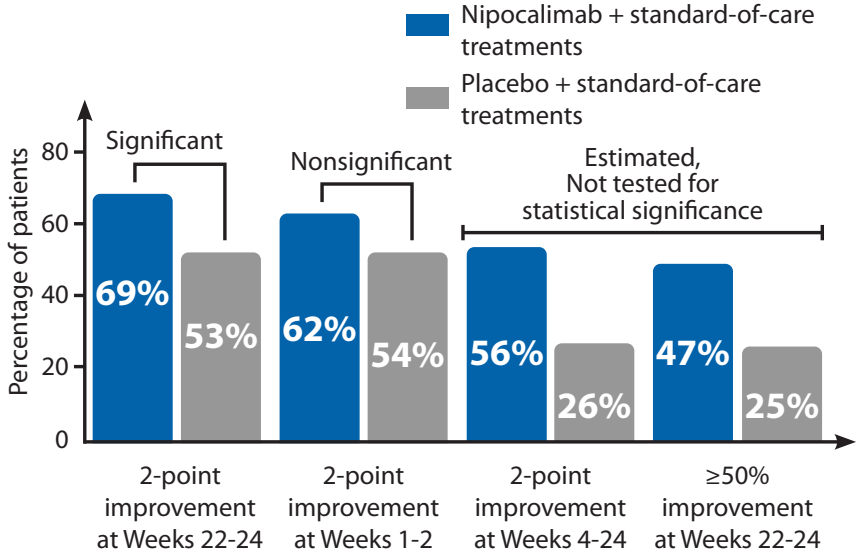
- **Key secondary endpoint 2:** Significantly greater proportion of patients in the nipocalimab group reached a 2-point or greater improvement in MG-ADL score at the end of treatment.
- **Key secondary endpoint 3:** A greater proportion of patients receiving nipocalimab had an early response (response at week 1, week 2, or week 1 and week 2) but the difference was not statistically significant.
- **Key secondary endpoints 4 & 5:** As the result for the third key secondary endpoint was not statistically significant, the two subsequent key secondary endpoints could not be formally tested according to the predefined testing sequence.
- Estimates for these endpoints showed a greater proportion of patients from nipocalimab group compared to placebo group:
  - » Maintained symptom improvement from week 4 to 24.
  - » Showed at least 50% symptom improvement over weeks 22, 23, and 24.

Results for other secondary endpoints based on MSE

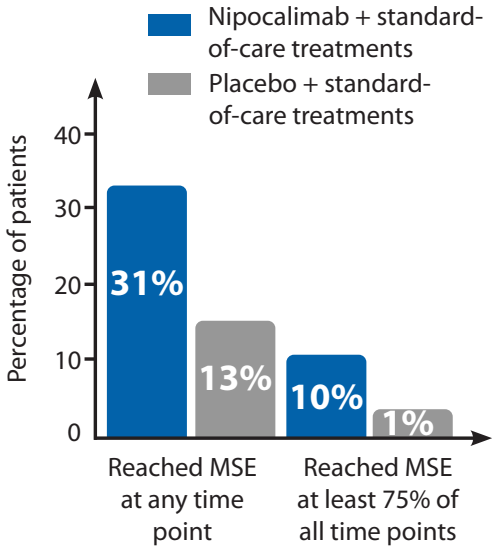
More patients from nipocalimab group compared to placebo group:

- Reached MSE at any time during the study.
- Reached MSE at least 75% of all time points during the study.

2-point improvement in MG-ADL



Achievement of MSE



Why does a clinically meaningful improvement matter for patients with gMG?

A 2-point improvement in the MG-ADL is considered a clinically meaningful change, which means there is a clinically noticeable improvement in function and patients may have greater independence in everyday life. For example, a patient improving by 2 points on breathing can mean going from having shortness of breath or difficulty catching their breath while resting (score of 2) to having normal breathing (score of 0).

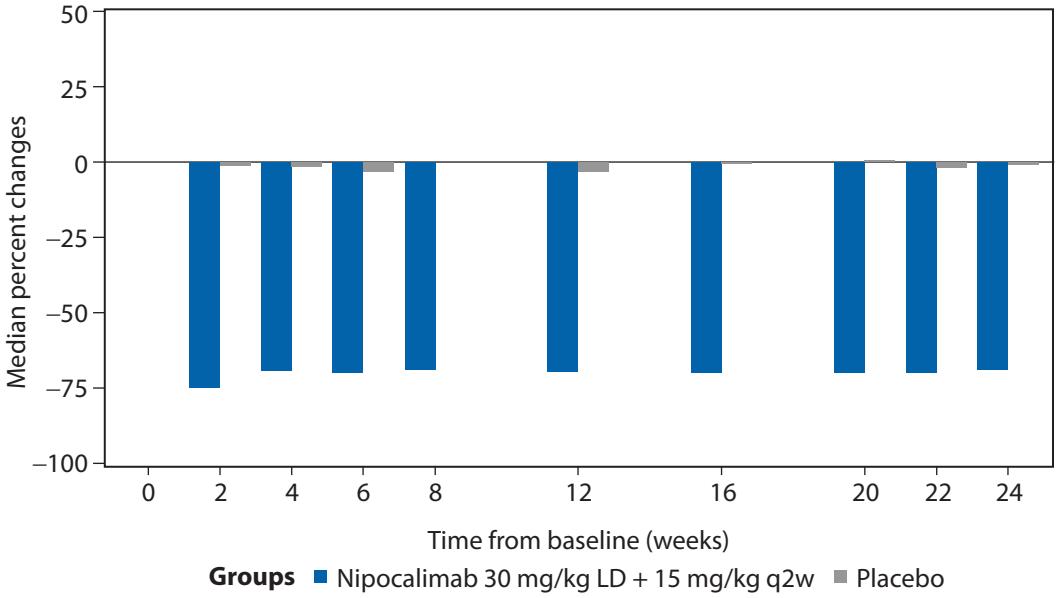
Making sense of this information

Longer bars (blue color) show that a higher percentage of patients treated with nipocalimab reached MSE at any time point and at least 75% of all time points, compared to those who received placebo.

Results for pharmacodynamic endpoints (lowering of IgG levels)

- Treatment with nipocalimab also led to a reduction in IgG antibodies, including harmful IgG autoantibodies against AChR and MuSK.
- Patients who received a placebo did not show these changes — their antibody levels remained high over the 24 weeks.

Median percent change from baseline IgG in the double-blind phase (Pharmacodynamic analysis set)



Immunoglobulin G was measured at week 2, 4, 6, 8, 12, 16, 20, 22 and week 24.
The median values of change from baseline for immunoglobulin in the placebo group at week 8 and 16 were close to 0 and not displayed in this graph.

Making sense of this information

The greater the bar graph, the greater is the median percent change from baseline in the level of IgG in the double blind phase. This reduction in overall immunoglobulin G is related to the reduction in harmful autoantibodies too.

Results for pharmacodynamic endpoints (antibody-positive patients)

Autoantibody-positive patients with gMG had a rapid, deep, and sustained reduction in IgG. This included reductions in autoantibodies.

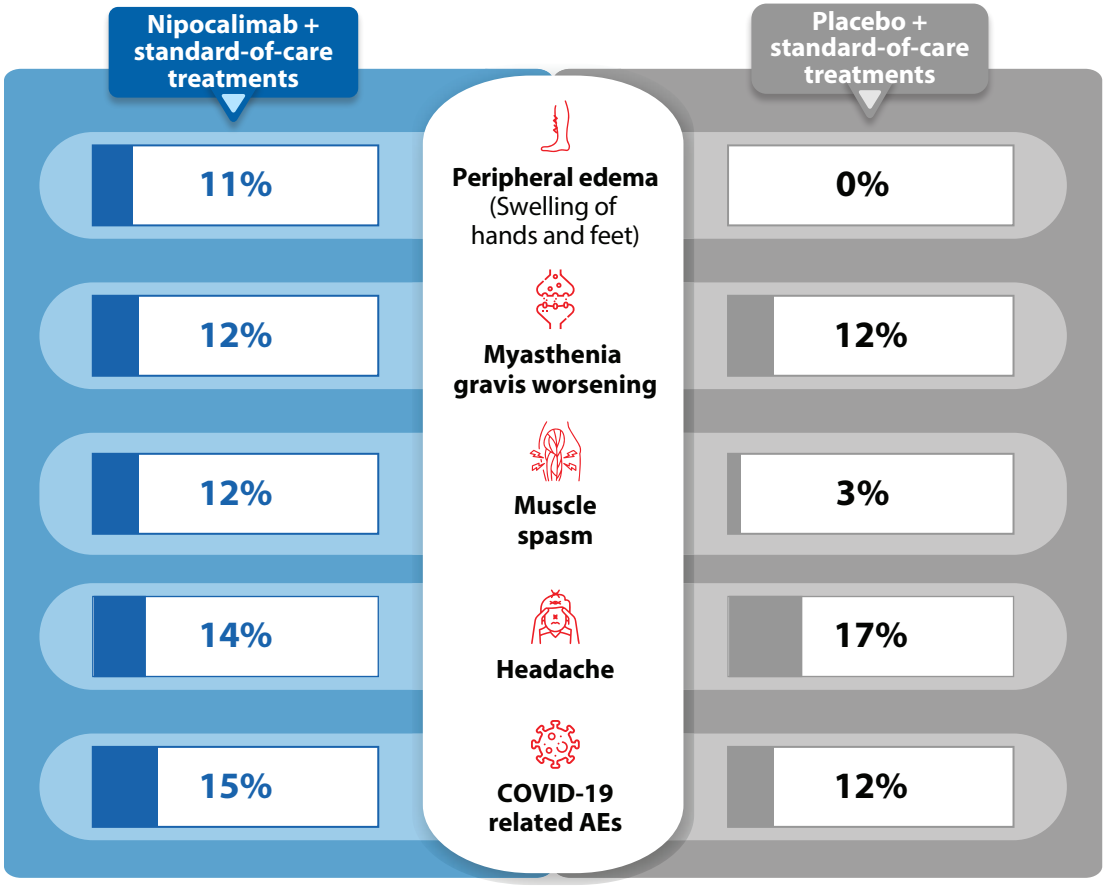
Overall, the results showed that nipocalimab reduced levels of harmful autoantibodies, helped reduce symptoms, and improved daily functioning in patients with gMG.

What were the most common side effects?

- Safety analysis was presented for safety analysis set (nipocalimab + standard-of-care treatments [98 participants] and placebo + standard-of-care treatments [98 participants]). The number of patients in the safety analysis set is larger than for efficacy because it includes patients with gMG who have undetectable antibodies.
- Patients in both the groups (nipocalimab and placebo) experienced side effects. Most side effects were mild or moderate in severity.
- There were 3 deaths during the study–1 in the nipocalimab group and 2 in the placebo group– but none were related to taking the study treatments according to their study doctor.
- Overall, nipocalimab was generally considered safe and did not lead to more serious or severe side effects compared with placebo.

	Side effects	Any serious side effects	Treatment related side effects	Side effects leading to permanent discontinuation of study treatment	Any infection	Severe infection or infection requiring invasive treatment
Nipocalimab + standard-of-care treatments (98 participants)	84%	9%	29%	5%	43%	3%
Placebo + standard-of-care treatments (98 participants)	84%	14%	29%	7%	43%	4%

Most frequently reported side effects



What are the take-home messages?

- Patients who received nipocalimab along with their standard-of-care treatments showed reduction in MG-ADL and QMG score, indicating improvements in their gMG signs and symptoms and improved daily functioning through 24 weeks of treatment.
- Nipocalimab was generally considered safe in patients during the study.
- This study is one of the largest and longest placebo-controlled studies of recently-evaluated drugs in gMG, and this study supports nipocalimab as a new treatment option for adult patients with gMG.
- The clinical study sites will continue to collect more data from the ongoing open-label extension study that will further help to understand how safe and effective nipocalimab is if used for longer than 6 months.

Where can readers find more information on this study?

The original article on which this summary is based on: Antozzi *et al.* Safety and efficacy of nipocalimab in adults with generalized myasthenia gravis (Vivacity-MG3): a phase 3, randomised, double-blind, placebo-controlled study. *Lancet Neurology* 2025; 24:105-116. doi: 10.1016/S1474-4422(24)00498-8. https://www.thelancet.com/journals/laneur/article/PIIS1474-4422(24)00498-8/abstract

The study took place from July 15, 2021 to November 17, 2023.

Trial registrations:

You can read more about Vivacity-MG3 study and find the list of clinical study sites at:

- ClinicalTrials.gov site: https://clinicaltrials.gov/study/NCT04951622. The trial identifier for this study is: NCT04951622
- EU Clinical Trials Register: https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2020-005732-29
  The trial identifier for this study is: 2020-005732-29

Additional resources

- https://www.neurology.org/doi/pdf/10.1212/WNL.0000000000207937 (Article on Phase 2 Vivacity MG study of nipocalimab in gMG)
- https://onlinelibrary.wiley.com/doi/epdf/10.1002/mus.28233
- https://index.mirasmart.com/AAN2025/PDFfiles/AAN2025-003606.html
- https://www.mdaconference.org/abstract-library/symptom-severity-assessment-using-mg-adl-items-and-domains-in-a-24-week-phase-3-study-vivacity-of-nipocalimab-in-generalized-myasthenia-gravis/

- https://index.mirasmart.com/AAN2025/PDFfiles/AAN2025-003608.html
- https://www.ean.org/fileadmin/user_upload/ean/Congress-2025/EAN2025_Congress_Abstract_Book.pdf (Abstract number ERP 305 and ERP 307)
- https://myasthenia.org/wp-content/uploads/2024/08/MGFAInternationalConferenceAbstractList_05.07.2025.pdf (Page 15–16)

Acknowledgments

The authors thank the study participants for their participation and Katie Abouzahr (Johnson & Johnson) for overall program guidance.

Disclosure statement

Sindhu Ramchandren, Eriene Youssef, Panna Sanga, Dan Huang, Yaowei Zhu, John J Sheehan, and Hong Sun are/were employees of Johnson & Johnson and might hold stock or stock options in Johnson & Johnson. Carlo Antozzi received funding for travel, meeting attendance, and advisory board participation from Alexion, Momenta, Sanofi, argenx, UCB, and Janssen Pharmaceuticals. Tuan Vu has received research or grant support related to myasthenia gravis from Alexion and AstraZeneca Rare Disease, Amgen, argenx, Cartesians, COUR, Dianthus, Immunovant, Johnson & Johnson, NMD Pharma, Regeneron, and UCB. TV serves as a consultant or on speaker bureaus for Alexion and AstraZeneca Rare Disease, Amgen, argenx, CSL Behring, Dianthus, Johnson & Johnson, and Takeda. Richard J Nowak has received research support from Alexion, AstraZeneca Rare Disease, argenx, Genentech, Grifols, Immunovant, Momenta Pharmaceuticals (now Janssen), the Myasthenia Gravis Foundation of America, the National Institutes of Health (National Institute of Neurological Disorders and Stroke and National Institute of Allergy and Infectious Diseases), Ra Pharmaceuticals (now UCB), and Viela Bio (Horizon Therapeutics, now Amgen), and has served as consultant or advisor for Alexion, AstraZeneca Rare Disease, argenx, Cour Pharmaceuticals, Immunovant, Momenta Pharmaceuticals (now Janssen), Ra Pharmaceuticals (now UCB), and Viela Bio (Horizon Therapeutics, now Amgen). Constantine Farmakidis has served as a consultant or advisor for argenx, Momenta and Janssen, the Muscular Dystrophy Association, and UCB. Vera Bril has received research support from AZ-Alexion, Grifols, CSL, UCB, argenx, Takeda, Octapharma, Akcea, Momenta (Johnson & Johnson), Immunovant, Ionis, and Viela. Jan De Bleecker has served on an advisory board for argenx, Alexion Pharmaceuticals, CSL, UCB Pharma, Janssen Pharmaceuticals, and Sanofi Genzyme. Teresa Sevilla has received honoraria for attendance at advisory boards from argenx, Alnylam, Pfizer, and UCB. Sarah Hoffmann has received speakers´ honoraria from Alexion, argenx, UCB, Grifols, Roche, and Janssen and honoraria for attendance at advisory boards from Alexion, argenx, and Roche. She is member of the medical advisory board of the German Myasthenia Society, DMG. Huan Yang, Eduard Minks, Jin-Sung Park, Mariusz Grudniak, Marek Smilowski, Kumaraswamy Sivakumar, and Yasushi Suzuki report no competing interests. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Writing support for this PLS-P was provided by Kalpana Tilekar, PhD from SIRO Medical Writing Pvt. Ltd., India, Amit Kavle and Mugdha Rokade provided the graphical designing support (SIRO Medical Writing Pvt. Ltd., India), with funding from Johnson & Johnson. Additional editorial support was provided by Doyel Mitra, PhD from Johnson & Johnson, Horsham, PA, USA.

Patient reviewers on this PLSP have received honorarium from *Future Neurology* for their review work but have no other relevant financial relationships to disclose.

Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

Funding

This study was sponsored by Johnson & Johnson. The sponsor contributed to study design, data collection and analysis, and decision to prepare and publish this article.

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