

Johnson & Johnson presents new data reinforcing sustained disease control and improved daily function achieved with IMAAVY® (nipocalimab-aahu) in generalized myasthenia gravis (gMG)

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- New two-year findings from the Phase 2/3 long-term extension demonstrate sustained disease control through two years, improvement in daily function and muscle strength, and reductions in corticosteroid use in anti-AChR^a adolescents
- Retrospective survey in adults identified fluctuating symptom control as a top driver for discontinuing prior advanced treatment, with most patient outcomes improving after transitioning to IMAAVY
- Data among 15 novel abstracts on IMAAVY to be presented at the MGFA Scientific Session during AANEM 2026

SPRING HOUSE, Pa., Sept. 29, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new findings on IMAAVY® (nipocalimab-aahu) for the treatment of generalized myasthenia gravis (gMG) across 15 novel abstracts to be presented at the 2026 Myasthenia Gravis Foundation of America (MGFA) Scientific Session and American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting. These data include two-year results from the Phase 2/3 study in adolescents which demonstrated sustained disease control while on IMAAVY, with patients maintaining improvements in daily function and muscle strength alongside reductions in corticosteroid use.¹ In addition, a retrospective survey of healthcare professionals (HCPs) treating adults with anti-AChR^a or anti-MuSK^b antibody-positive gMG provides insight into how fluctuating symptoms and the resulting unmet need for more sustained disease control can drive transitions from one advanced therapy to another.²

Long-term data demonstrated sustained disease control in adolescents with gMG

Two-year findings from the Vibrance-MG Phase 2/3 long-term extension study showed sustained disease control in adolescents living with anti-AChR+ gMG alongside continued reductions in corticosteroid use. These findings are consistent with improvements observed in adults in the **open-label extension** of the Phase 3 Vivacity-MG3 study:¹

- Daily function and muscle strength improvements were sustained through Week 108: Among participants with available data, mean changes from baseline were –2.88 points in MG-ADL^c and –8.25 points in QMG^d at Week 108 consistent with findings at Week 4, 24 and at all intervening time points through two years.
- Corticosteroid reductions were observed: Of the six adolescent patients taking corticosteroids at study entry, three reduced their dose while one discontinued after two years on IMAAVY.
- No new safety signals were identified through up to two years of treatment: The safety profile of IMAAVY in adolescents was similar to that reported in adults.

"For adolescents living with generalized myasthenia gravis, unpredictable muscle weakness and symptoms such as eyelid droop and double vision can affect more than physical health; they can disrupt school, friendships and their growing independence," said Jonathan Strober, M.D., Director, Pediatric Neuromuscular Program and Neuromuscular Clinic Sponsored by the MDA.^e "The two-year Vibrance-MG results are encouraging and add to our growing body of evidence of IMAAVY in adolescents with continued improvements in daily function, muscle strength and reductions in corticosteroid use observed over time."

Need for sustained disease control drives treatment transitions

Findings from a retrospective survey^f of HCPs treating adults with anti-AChR+ or anti-MuSK+ gMG highlight how the need for more sustained disease control can shape treatment decisions—from dissatisfaction with fluctuating symptoms on a prior advanced therapy, to seeking improved efficacy and a consistent treatment schedule when initiating IMAAVY:²

- Fluctuating symptom control was the most common driver for discontinuing prior therapy: HCPs cited fluctuating symptom control (54.6%) suggesting that a lack of sustained disease control remains an important unmet need shaping treatment decisions.
- Consistent treatment schedule and hope for improved efficacy were the top drivers for initiating IMAAVY: Among 97 patients who transitioned from prior advanced therapies to IMAAVY, HCPs most frequently cited preference for a consistent treatment schedule (62.9%) and hope for improved efficacy (56.7%) as reasons for initiating IMAAVY.
- Positive outcomes reported following transition to IMAAVY: HCPs reported that 73.2% of patients were "much improved" or "very much improved," while 76.4% of patients receiving prednisone reduced their dose and 5.5% discontinued use—an important treatment objective for people living with gMG.

"People living with generalized myasthenia gravis can experience fluctuating symptoms that make sustained

disease control an important treatment goal. The HCP survey findings provide important insight into the factors shaping treatment decisions, with fluctuating symptom control emerging as the leading reason healthcare professionals reported for discontinuing prior therapy," said David M. Lee, M.D., Ph.D., Global Immunology Therapeutic Area Head, Johnson & Johnson. "The broader clinical evidence for IMAAVY across adolescents and adults, including reductions in corticosteroid use, further informs our understanding of the potential for IMAAVY to deliver sustained disease control across a broad population of people living with gMG."

IMAAVY is an immunoselective treatment designed to substantially reduce pathogenic immunoglobulin G (IgG), a root cause of gMG, while preserving B-cell function. It is currently the only FcRn blocker approved for pediatric patients (12 years of age and older) with anti-AChR or anti-MuSK antibody-positive gMG by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).^{3,4}

Editor's notes:

- a. Anti-AChR+ = anti-acetylcholine receptor positive antibody.
- b. Anti-MuSK+ = anti-muscle specific tyrosine kinase positive antibody.
- c. MG-ADL (Myasthenia Gravis – Activities of Daily Living) provides a rapid clinical assessment of the patient's recall of symptoms impacting activities of daily living, with a total score range of 0 to 24; a higher score indicates greater symptom severity.⁵
- d. QMG (Quantitative Myasthenia Gravis) is a 13-item assessment by a clinician that quantifies MG disease severity. The total QMG score ranges from 0 to 39, where higher scores indicate greater disease severity.⁶
- e. Dr. Jonathan Strober has provided consulting, advisory, and speaking services to Johnson & Johnson. He has not been paid for any media work.
- f. The treatment-switch findings are based on a retrospective, 21-item electronic survey of U.S. neurology HCPs. Eligible HCPs had switched at least one adult with gMG from a prior advanced therapy such as IVIG, an anti-CD19 therapy, complement inhibitor or other FcRn inhibitor; respondents reviewed medical records and reported de-identified data from 97 patients. As findings relied on HCP reporting and retrospective medical record review, they may be subject to information and recall bias. The convenience sample of HCPs may also limit generalizability to broader clinical settings and patient populations, while the cross-sectional design does not allow conclusions about long-term trends or causal relationships.

About generalized myasthenia gravis (gMG)

Myasthenia gravis (MG) is an autoantibody disease in which the immune system mistakenly makes antibodies (e.g., anti-acetylcholine receptor [AChR], anti-muscle-specific tyrosine kinase [MuSK]), which target proteins at the neuromuscular junction and can block or disrupt normal signaling from nerves to muscles, thus impairing or

preventing muscle contraction.^{7,8} The disease impacts an estimated 700,000 people worldwide.⁹ The disease affects both men and women and occurs across all ages and racial and ethnic groups, but it most frequently starts in young women and older men.¹⁰ Roughly 50% of individuals diagnosed with MG are women, and about one in five of those women are of child-bearing potential.^{10,11,12} Approximately 10 to 15% of new cases of MG are diagnosed in pediatric patients 12-17 years of age.^{12,13,14,15} Among juvenile MG patients, girls are affected more often than boys, with over 65% of pediatric MG cases in the U.S. diagnosed in girls.^{16,17,18}

Initial disease manifestations are usually eye-related, but approximately 85% of MG patients experience additional advancements to the disease manifestations, referred to as generalized myasthenia gravis (gMG).^{19,20,21,22,23,24} This is characterized by severe muscle weakness and difficulties in speech and swallowing.^{20,21,22,23,24} Approximately 100,000 individuals in the U.S. are living with gMG.²⁵ Vulnerable gMG populations, such as pediatric patients, have more limited therapeutic options.²⁶

About the Phase 2/3 Vibrance-MG study

The Phase 2/3 Vibrance-MG study (NCT05265273) is an ongoing open-label study to determine the effect of nipocalimab in pediatric participants with gMG.²⁷ Seven participants aged 12-17 years with a diagnosis of gMG as reflected by a Myasthenia Gravis Foundation of America (MGFA) Class of II through IV at screening, and an insufficient clinical response to ongoing, stable SOC therapy, have been enrolled in the trial.²⁸ Participants must have a positive blood test for either anti-AChR or anti-MuSK autoantibodies.²⁸ The study consists of a screening period of up to four weeks, a 24-week open-label active-treatment phase during which participants receive nipocalimab intravenously every two weeks, and a long-term extension phase; a safety follow-up assessment will be conducted at eight weeks after last dose.²⁸ The primary endpoint of the study is the effect of nipocalimab on total serum IgG, safety and tolerability, and pharmacokinetics in pediatric participants with gMG at 24 weeks. Secondary endpoints include change in MG-ADL and QMG scores at 24 weeks.^{28,29}

About IMAAVY® (nipocalimab-aahu)

IMAAVY is an immunoselective treatment designed to target, bind with high affinity, and block the neonatal Fc receptor (FcRn), reducing circulating immunoglobulin G (IgG) antibodies that drive disease while also preserving B-cell function based on in vitro and/or in vivo studies.^{29,30,31} IMAAVY is currently approved for the treatment of generalized myasthenia gravis (gMG) in adults and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.⁴ IMAAVY is also approved for the treatment of warm autoimmune hemolytic anemia (wAIHA) in adult and pediatric patients 12 years of age and older currently or previously treated with corticosteroids.⁴

Nipocalimab is being investigated across three key segments in the autoantibody space including Rheumatologic

diseases, Rare Autoantibody diseases, and Maternal Fetal diseases mediated by maternal alloantibodies, in which blockade of IgG binding to FcRn in the placenta is believed to limit transplacental transfer of maternal alloantibodies to the fetus.^{32,33,34,35,36,37,38,39,40,41}

The U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have granted several key designations to nipocalimab including:

- EU EMA Orphan medicinal product designation for hemolytic disease of the fetus and newborn (HDFN) in October 2019 and fetal and neonatal alloimmune thrombocytopenia (FNAIT) in April 2025
- U.S. FDA Fast Track designation in HDFN, and warm autoimmune hemolytic anemia (wAIHA) in July 2019, gMG in December 2021, FNAIT in March 2024, Sjögren's disease (SjD) in March 2025, and systemic lupus erythematosus (SLE) in January 2026
- U.S. FDA Orphan drug status for wAIHA in December 2019, HDFN in June 2020, gMG in February 2021, chronic inflammatory demyelinating polyneuropathy (CIDP) in October 2021 and FNAIT in December 2023
- U.S. FDA Breakthrough Therapy designation for HDFN in February 2024 and for SjD in November 2024
- U.S. FDA granted Priority Review in gMG in Q4 2024 and wAIHA in Q2 2026

The legal manufacturer for IMAAVY is Janssen Biotech, Inc.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about IMAAVY?

IMAAVY is a prescription medicine that may cause serious side effects, including:

- Infections. IMAAVY may increase your risk of infections, including serious infections. If you have an infection, your healthcare provider will treat your infection or delay your infusion until your infection is gone. Tell your healthcare provider right away if you have any of the following infection symptoms:

-
- fever
 - chills
 - shivering
 - cough

- sore throat
- fever blisters
- burning when you urinate
- trouble breathing

- Allergic (hypersensitivity) reactions can happen during or up to a few weeks after your IMAAVY infusion. Tell your healthcare provider and get emergency medical help right away if you get any of these symptoms during

or after your IMAAVY infusion:

-
- a swollen face, lips, mouth, tongue, or throat
 - trouble swallowing or breathing

- hives
- itchy rash
- chest pain or tightness

- Infusion-related reactions. Tell your healthcare provider right away if you get any of these symptoms during or within a few days after your IMAAVY infusion:

-
- headache
 - rash
 - nausea
 - fatigue

- dizziness
- chills
- flu-like symptoms
- redness of skin

Do not receive IMAAVY if you have a history of a severe allergic reaction to nipocalimab-aahu or any of the ingredients in IMAAVY. Reactions have included angioedema and anaphylaxis. Refer to the Patient Information section of the Prescribing Information for a complete list of ingredients in IMAAVY.

Before receiving IMAAVY, tell your healthcare provider about all of your medical conditions, including if you:

- have had an allergic reaction to IMAAVY.
- have or had any recent infections or symptoms of infection.
- have or had shingles (herpes zoster) or mono (mononucleosis caused by Epstein-Barr virus).
- have recently received or are scheduled to receive an immunization (vaccine). People who take IMAAVY should not receive live vaccines.
- are pregnant or plan to become pregnant. It is not known if IMAAVY will harm your unborn baby.
 - **Pregnancy Safety Study.** There is a pregnancy safety study for IMAAVY. If IMAAVY is given during pregnancy or you become pregnant while receiving IMAAVY, your healthcare provider should report IMAAVY exposure by contacting Janssen at **1-800-526-7736**.
- are breastfeeding or plan to breastfeed. IMAAVY can pass into your breast milk. It is not known if IMAAVY will harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with IMAAVY.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of IMAAVY?

IMAAVY may cause serious side effects. See "What is the most important information I should know about IMAAVY?"

The most common side effects in people with gMG treated with IMAAVY include: respiratory tract infection, peripheral edema (swelling in your hands, ankles, or feet), and muscle spasms.

The most common side effects in people with wAIHA treated with IMAAVY include: peripheral edema (swelling in your hands, ankles, or feet), diarrhea, and pyrexia (fever).

These are not all the possible side effects of IMAAVY. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see the full **Prescribing Information** and **Patient Information** for IMAAVY and discuss any questions you have with your doctor.

Dosage Form and Strengths: IMAAVY is supplied as a 300 mg/1.62 mL and a 1,200 mg/6.5 mL (185 mg/mL) single-dose vial per carton for intravenous injection.

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow and profoundly impact health for humanity.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of IMAAVY. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com, www.investor.jnj.com or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

REFERENCES

¹ Vu T, et al. Two year follow-up results of nipocalimab in adolescents with Generalized myasthenia gravis during active-treatment and Long-term extension phases: vibrance-mg phase 2/3 study. Presented at the 2026 American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting and 2026 Myasthenia Gravis Foundation of America (MGFA) Scientific Session. Poster #25.

² Kutz C, et al. Retrospective Review of Treatment Switches to Nipocalimab in Generalized Myasthenia Gravis: Real-World Healthcare Provider Perspectives. Presented at the 2026 American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting and 2026 Myasthenia Gravis Foundation of America (MGFA) Scientific Session. Poster #55.

³ IMAAVY® U.S. Prescribing Information. Available at:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761430s000lbl.pdf. Last accessed: September 2026.

⁴ European Medicines Agency. IMAAVY® Summary of Product Characteristics. Available

at: https://www.ema.europa.eu/en/documents/product-information/imaavy-epar-product-information_en.pdf. Last accessed: September 2026

⁵ Wolfe GI. Myasthenia gravis activities of daily living profile. *Neurology*. 1999;22;52(7):1487-9.

⁶ Yin, J et al. A multicenter, randomized, open-label, phase 2 clinical study of telitacicept in adult patients with generalized myasthenia gravis. *Eur J Neurol*. 2024;31(8):e16322.

⁷ Bacci, ED et al. Understanding side effects of therapy for myasthenia gravis and their impact on daily life. *BMC Neurol*. 2019;19(1):335.

⁸ Wiendl, H et al. Guideline for the management of myasthenic syndromes. *Ther Adv Neurol Disord*. 2023; 16:17562864231213240.

⁹ Chen J, Tian D-C, Zhang C, et al. Incidence, mortality, and economic burden of myasthenia gravis in China: A nationwide population-based study. *The Lancet Regional Health - Western Pacific*.

¹⁰ Ye, Yun et al. Epidemiology of myasthenia gravis in the United States. *Frontiers in neurology* vol. 15 1339167. 16 Feb. 2024.

¹¹ Dresser, Laura et al. Myasthenia Gravis: Epidemiology, Pathophysiology and Clinical Manifestations. *Journal of clinical medicine* vol. 10,11 2235. 21 May. 2021.

¹² J&J. Data on file.

¹³ Evoli A, et al. Juvenile myasthenia gravis with prepubertal onset. *Neuromuscul Disord*. 1998 Dec;8(8):561-7.

¹⁴ Evoli A. Acquired myasthenia gravis in childhood. *Curr Opin Neurol*. 2010 Oct;23(5):536-40.

¹⁵ Finnis MF, Jayawant S. Juvenile myasthenia gravis: a paediatric perspective. *Autoimmune Dis*. 2011; 2011:404101.

¹⁶ Haliloglu G, et al. Gender prevalence in childhood multiple sclerosis and myasthenia gravis. *J Child Neurol*. 2002 May;17(5):390-2.

¹⁷ Parr JR, et al. How common is childhood myasthenia? The UK incidence and prevalence of autoimmune and congenital myasthenia. *Arch Dis Child*. 2014 Jun;99(6):539-42.

¹⁸ Mansukhani SA, et al. Incidence and Ocular Features of Pediatric Myasthenias. *Am J Ophthalmol*. 2019 Apr; 200:242-249.

¹⁹ Law, N et al. The Lived Experience of Myasthenia Gravis: A Patient-Led Analysis. *Neurol Ther*. 2021;10(2):1103-1125.

²⁰ National Institute of Neurological Disorders and Stroke. Myasthenia Gravis. Available at: <https://www.ninds.nih.gov/health-information/disorders/myasthenia-gravis> Last accessed: September 2026.

²¹ Bever, CT et al. (1983), Prognosis of ocular myasthenia. *Ann Neurol*. 1983;14(5):516-9.

²² Kupersmith, MJ et al. Development of generalized disease at 2 years in patients with ocular myasthenia gravis. *Arch Neurol*. 2003;60(2):243-8.

²³ National Institute of Neurological Disorders and Stroke. Myasthenia gravis fact sheet. Available at: https://www.ninds.nih.gov/sites/default/files/migrate-documents/myasthenia_gravis_e_march_2020_508c.pdf. Last accessed: September 2026.

²⁴ Cleveland Clinic. Myasthenia Gravis: Treatment & Symptoms. Available at:

<https://my.clevelandclinic.org/health/diseases/17252-myasthenia-gravis-mg>. Last accessed: September 2026.

²⁵ DRG EPI (2021) & Optum Claims Analysis Jan 2012-December 2020.

²⁶ O'Connell K, Ramdas S, Palace J. Management of Juvenile Myasthenia Gravis. *Front Neurol*. 2020 Jul 24;11:743.

²⁷ ClinicalTrials.gov. NCT05265273. Available at: <https://clinicaltrials.gov/study/NCT05265273>. Last accessed: September 2026.

²⁸ Strober J et al. Safety and effectiveness of nipocalimab in adolescent participants in the open label Phase 2/3 Vibrance-MG clinical study. Presentation at American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting. October 2024.

²⁹ Seth, N et al. Nipocalimab, an immunoselective FcRn blocker that lowers IgG and has unique molecular properties. *MAbs*. 2025;17(1):2461191

³⁰ Zhu, LN et al. FcRn inhibitors: a novel option for the treatment of myasthenia gravis. *Neural Regen Res*. 2023;18(8):1637-1644.

³¹ Ling, LE et al. M281, an anti-fcrn antibody: Pharmacodynamics, pharmacokinetics, and safety across the full range of IGG reduction in a first-in-human study. *Clinical Pharmacology & Therapeutics*. 2018;105(4):1031–1039.

³² ClinicalTrials.gov. Identifier: NCT03842189. Available at: <https://clinicaltrials.gov/ct2/show/NCT03842189>. Last accessed: September 2026.

³³ ClinicalTrials.gov Identifier: NCT05327114. Available at: <https://www.clinicaltrials.gov/study/NCT05327114>. Last accessed: September 2026.

³⁴ ClinicalTrials.gov Identifier: NCT04119050. Available at: <https://clinicaltrials.gov/study/NCT04119050>. Last accessed: September 2026.

³⁵ ClinicalTrials.gov Identifier: NCT05379634. Available at: <https://clinicaltrials.gov/study/NCT05379634>. Last accessed: September 2026.

³⁶ ClinicalTrials.gov Identifier: NCT05912517. Available at: <https://www.clinicaltrials.gov/study/NCT05912517>. Last accessed: September 2026.

³⁷ ClinicalTrials.gov Identifier: NCT04968912. Available at: <https://clinicaltrials.gov/study/NCT04968912>. Last accessed: September 2026.

³⁸ ClinicalTrials.gov Identifier: NCT04882878. Available at: <https://clinicaltrials.gov/study/NCT04882878>. Last accessed: September 2026.

³⁹ ClinicalTrials.gov Identifier: NCT06449651. Available at: <https://clinicaltrials.gov/study/NCT06449651>. Last accessed: September 2026.

⁴⁰ ClinicalTrials.gov Identifier: NCT06533098 Available at: <https://clinicaltrials.gov/study/NCT06533098>. Last accessed: September 2026.

⁴¹ ClinicalTrials.gov Identifier: NCT04951622. Available at: <https://clinicaltrials.gov/ct2/show/NCT04951622> Last accessed: September 2026.

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