

Johnson & Johnson receives FDA approval for IMAAVY™ (nipocalimab-aahu), a new FcRn blocker offering long-lasting disease control in the broadest population of people living with generalized myasthenia gravis (gMG)

2025-04-30

First and only FcRn blocker approved in anti-AChR and anti-MuSK antibody positive adults and pediatric gMG patients aged 12 and older

IMAAVY delivered rapid and substantial reduction in immunoglobulin G (IgG) levels, one of the root causes of gMG, in both the adult and pediatric pivotal studies

gMG patients taking IMAAVY demonstrated 20 months of lasting disease control and symptom relief in the pivotal Vivacity-MG3 study and ongoing open-label extension (OLE)

SPRING HOUSE, Pa., April 30, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced that the U.S. Food and Drug Administration (FDA) has approved IMAAVY™ (nipocalimab-aahu), a human FcRn-blocking monoclonal antibody, for the treatment of generalized myasthenia gravis (gMG). The approval, which follows **FDA Priority Review designation**, offers a new treatment option in a proven class with the potential for lasting disease control in the broadest population of people living with gMG (adults and pediatric patients 12 years of age and older who are anti-acetylcholine receptor [AChR] or anti-muscle-specific kinase [MuSK] antibody positive).¹

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"We consistently hear from individuals living with myasthenia gravis who are hopeful for new treatment options that may help bring greater stability, independence and predictability to their lives," said Samantha Masterson, President and CEO, Myasthenia Gravis Foundation of America.^a "Today's announcement provides another option which could help address the constant uncertainty and heavy physical and mental toll that MG symptom relapse presents to patients and their families."

gMG is a chronic, debilitating autoantibody disease for which significant unmet patient need exists for additional efficacious therapies with demonstrated safety profiles that offer sustained disease control.^{2,3} Anti-AChR and anti-MuSK antibody positive individuals comprise $\geq 90\%$ of the total antibody-positive gMG population.⁴ IMAAVY is an immunoselective therapy designed to substantially reduce immunoglobulin G (IgG), including harmful IgG autoantibodies, without additional detectable effects on other adaptive and innate immune functions.⁵

The approval is supported by data from the pivotal, ongoing Vivacity-MG3 study – the longest primary endpoint of a registrational trial of any FcRn blocker in adults with living with gMG. Highlights of the study include⁴:

- IMAAVY plus standard of care (SOC) provided superior disease control throughout 24 weeks when compared to placebo plus SOC, as measured by improvement in the MG-ADL^b score.⁴ This translates into patients regaining essential daily functions, such as chewing, swallowing, speaking and breathing.⁴
- Participants on IMAAVY plus SOC maintained improvements out to 20 months of follow-up in the ongoing open-label extension (OLE) study in gMG.⁶
- IMAAVY demonstrated a rapid and sustained reduction in autoantibody levels by up to 75% from the first dose and throughout a 24-week period of monitoring.⁴

"The clinical results we've seen with IMAAVY represent a significant milestone in the treatment of gMG," said Dr. Nicholas J. Silvestri, M.D., Professor of Neurology at University of Buffalo^d "Patients experienced substantial symptom relief and lasting disease control that translated into better daily function and did not fade over 24 weeks in the pivotal Vivacity-MG3 study. Having a treatment that delivers this level of durable symptom stability is a meaningful step forward for managing a complex and unpredictable disease like gMG, and to have it in both AChR+ and MuSK+ adults and pediatric patients 12 years and older brings an additional FcRn treatment to a broader range of patients."

Results from the ongoing Vibrance Phase 2/3 pediatric study in anti-AChR and anti-MuSK antibody positive adolescents aged 12-17 years showed that IMAAVY plus SOC met its primary endpoint with a 69% reduction in total serum IgG over 24 weeks, and secondary endpoints of improvements in MG-ADL and QMG^c scales.⁷

IMAAVY has demonstrated a consistent safety profile across both Vivacity-MG3 and the ongoing Vibrance-MG studies, with comparable tolerability in adult and pediatric populations.^{3,4}

"Today's FDA approval of IMAAVY marks a historic milestone for the more than 240 million patients suffering with autoantibody diseases, many with few or no approved targeted treatments," said David Lee, M.D., Ph.D., Global Immunology Therapeutic Area Head, Johnson & Johnson Innovative Medicine. "This approval is the result of years of scientific commitment, collaboration and determination for our nipocalimab program, and we're proud to bring this new treatment option to patients living with anti-AChR or anti-MuSK antibody positive gMG."

Johnson & Johnson is committed to supporting affordable access to all its treatments, including offering a patient support program called IMAAVY withMe in the United States. With this program, commercially insured patients who are prescribed IMAAVY may be eligible to receive their first treatment in as quickly as one week and may pay as little as \$0 per infusion.

Health authority submissions seeking approval for nipocalimab in the treatment of gMG are currently under review with numerous regulatory authorities worldwide.

Editor's notes:

a. Ms. Masterson has not been paid for any media work.

b. 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.⁸

c. 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 indicated greater disease severity.⁸

d. Dr. Nicholas J. Silvestri, M.D. has provided consulting, advisory, and speaking services to Johnson & Johnson. He has not been paid for any media work.

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.^{2,9,10} The disease impacts an estimated 700,000 people worldwide.² The disease affects both men and women and occurs across all ages, racial and ethnic groups, but most frequently starts in young women and older men.¹¹ Roughly 50 percent of individuals diagnosed with MG are women, and about one in five of those women are of child-bearing potential.^{12,13,14} Approximately 10 to 15% of new cases of MG are

diagnosed in pediatric patients 12-17 years of age.^{15,16,17} 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.^{18,19,20}

Initial disease manifestations are usually eye-related but approximately 85 percent of MG patients experience additional advancements to the disease manifestations—referred to as generalized myasthenia gravis (gMG). This is characterized by severe muscle weakness and difficulties in speech and swallowing.^{21,22,23,24,25} Approximately 100,000 individuals in the U.S. are living with gMG.²⁶ Vulnerable gMG populations, such as pediatric patients, have more limited therapeutic options.²⁷

ABOUT THE PHASE 3 VIVACITY-MG3 STUDY

The Phase 3 Vivacity-MG3 study (**NCT04951622**) was specifically designed to measure sustained efficacy and safety with consistent dosing in this unpredictable chronic condition where unmet need remains high. Antibody positive or negative adult gMG patients with insufficient response (MG-ADL ≥ 6) to ongoing SOC therapy were identified and 199 patients, 153 of whom were antibody positive, enrolled in the 24-week double-blind placebo-controlled trial.^{4,28} Randomization was 1:1, nipocalimab plus current SOC (30 mg/kg IV loading dose followed by 15 mg/kg every two weeks) or placebo plus current SOC.⁴ Baseline demographics were balanced across arms (77 nipocalimab, 76 placebo).⁴ The primary efficacy endpoint was the comparison of the mean change from baseline to Weeks 22, 23, and 24 between treatment groups in the MG-ADL total score.⁴ A key secondary endpoint included change in QMG score. Long-term safety and efficacy were further assessed in an ongoing open-label extension (OLE) phase.²⁸

ABOUT THE PHASE 2/3 VIBRANCE-MG STUDY

The Phase 2/3 Vibrance-MG study (**NCT05265273**) is an on-going open-label study to determine the effect of nipocalimab in pediatric participants with gMG.²⁹ 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.³⁰ Participants must have a positive blood test for either anti-AChR or anti-MUSK autoantibodies. 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.²⁹ The primary outcome 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.^{29,30}

ABOUT IMAAVY™ (nipocalimab-aahu)

IMAAVY is a monoclonal antibody, designed to bind with high affinity to block FcRn and reduce levels of circulating

immunoglobulin G (IgG) antibodies that underlie generalized myasthenia gravis (gMG) without additional detectable effects on other adaptive and innate immune functions. IMAAVY is currently approved for the treatment of gMG in adults and pediatric patients 12 years of age and older who are AChR or MuSK antibody positive.¹

Nipocalimab is continuing to be investigated across three key segments in the autoantibody space including Rare Autoantibody diseases, Maternal Fetal diseases mediated by maternal alloantibodies and Rheumatic diseases.^{28,31,32,33,34,35,36,37,38,39} The investigational monoclonal antibody is designed to bind with high affinity to block FcRn and reduce levels of circulating immunoglobulin G (IgG) auto and alloantibodies potentially without additional detectable effects on other adaptive and innate immune functions.

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

- U.S. FDA Fast Track designation in hemolytic disease of the fetus and newborn (HDFN) and warm autoimmune hemolytic anemia (wAIHA) in July 2019, gMG in December 2021, fetal and neonatal alloimmune thrombocytopenia) FNAIT in March 2024 and Sjögren's disease (SjD) in March 2025
- 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 Sjögren's disease in November 2024
- U.S. FDA granted Priority Review in gMG in Q4 2024
- EU EMA Orphan medicinal product designation for HDFN in October 2019

WHAT IS IMAAVY™ (nipocalimab-aahu)?

IMAAVY™ is a prescription medicine used to treat adults and children 12 years of age and older with a disease called generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

It is not known if IMAAVY™ is safe and effective in children under 12 years of age.

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 are a common side effect of IMAAVY™ that can be serious. Receiving IMAAVY™ may increase your

risk of infection. 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
- Allergic (hypersensitivity) reactions may happen during or up to a few weeks after your IMAAVY™ infusion. 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
 - difficulty swallowing or breathing
 - itchy rash (hives)
 - chest pain or tightness
 - Infusion-related reactions are possible. Tell your healthcare provider right away if you get any of these symptoms during or 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 severe allergic reaction to nipocalimab-aahu or any of the ingredients in IMAAVY™. Reactions have included angioedema and anaphylaxis.

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

- ever had an allergic reaction to IMAAVY™.
- have or had any recent infections or symptoms of infection.
- have recently received or are scheduled to receive an immunization (vaccine). People who take IMAAVY™ should not receive live vaccines.
- are pregnant, plan to become pregnant, or are breastfeeding. It is not known whether IMAAVY™ will harm

your 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 or www.IMAAVY.com.

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 of IMAAVY™ include: respiratory tract infection, peripheral edema (swelling in your hands, ankles, or feet), and muscle spasms.

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 **Medication Guide** 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

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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 Janssen Research & Development, LLC, Janssen Biotech, Inc. and/or 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 or on request from Johnson & Johnson. None of Janssen Research & Development, LLC, Janssen Biotech, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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Media contact:
Bridget Kimmel
bkimmel@its.jnj.com

Investor contact:
Lauren Johnson
investor-relations@its.jnj.com

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