

Johnson & Johnson presents new IMAAVY® (nipocalimab-aahu) data at European Academy of Neurology (EAN) 2026 Congress reinforcing sustained disease control in generalized myasthenia gravis

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- New analyses from the Phase 3 Vivacity-MG3 study support the impact of IMAAVY in anti-AChR^a, anti-MuSK^b adult patients with generalized myasthenia gravis (gMG) including those early in their disease, participants with lower symptom burden and those who experienced common infections
- To address an important evidence gap, the PETUNIA^c study design will be presented – demonstrating the innovative way pregnancy outcomes data will be collected following treatment with IMAAVY
- IMAAVY, an immunoselective neonatal Fc receptor (FcRn) blocker, is designed to target and reduce pathogenic immunoglobulin G (IgG) autoantibodies associated with generalized myasthenia gravis (gMG)

GENEVA, June 26, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new data across 12 abstracts at the European Academy of Neurology (EAN) 2026 Congress that offer additional insight into the use of IMAAVY® (nipocalimab-aahu) throughout clinically relevant points in the generalized myasthenia gravis (gMG) treatment journey. The analyses include adults with anti-AChR^a or anti-MuSK^b antibody-positive gMG who were early in their disease course or had lower baseline symptom burden – providing insight into the potential importance of addressing pathogenic immunoglobulin G (IgG) early in disease progression where use of advanced therapies may be less common.^{1,2} Additional research to be shared include outcomes shortly after common infections, which are a known cause of disease exacerbations in gMG, and plans to address evidence gaps in use of IMAAVY during pregnancy.^{3,4}

"For many people living with generalized myasthenia gravis, achieving and maintaining sustained disease control is an important goal throughout the course of their disease, from the moment they are diagnosed and across the

different stages of their journey," said Carlo Antozzi, M.D., Neurological Institute Foundation C. Besta of Milan, Italy.^d "These post-hoc analyses add to the growing body of evidence on IMAAVY, which is designed to selectively target and bind the neonatal Fc receptor with high affinity, and reduce pathogenic immunoglobulin G autoantibodies associated with generalized myasthenia gravis."

Post-hoc analyses from the pivotal Vivacity-MG3 study in adults with antibody positive gMG (spanning anti-AChR+ and anti-MuSK+) will be presented which provide new insights that could inform clinical care including:

- Patients early in their disease course (within five years of diagnosis) show improved outcomes: IMAAVY plus standard of care (SOC) showed greater reductions in MG-ADL^e scores versus placebo plus SOC (-4.9 vs. -2.7) at Week 24, with a greater proportion of patients receiving IMAAVY also achieving the stringent measure of sustained meaningful clinical improvement (MCI)^f for ≥20 weeks compared to placebo.^{1,5} IMAAVY is the only FcRn blocker evaluated to demonstrate sustained MCI over this duration in the double-blind phase of its pivotal study.^{5,g}
- Patients with lower baseline symptom burden sustain MCI: IMAAVY plus SOC decreased symptom severity^h and improved daily functioning at Week 24 versus placebo plus SOC (MG-ADL scores of -4.5 vs. -2.3).² A greater proportion of patients receiving IMAAVY also achieved sustained MCI in this setting, adding further insights for healthcare professionals into the use of IMAAVY in patients with less severe disease.^{6,i}
- Patients maintain control after contracting common infections: In the IMAAVY arm, observed symptom improvements were maintained within two weeks after patients contracted common infections, providing data on the use of IMAAVY after periods when the likelihood of disease exacerbations is elevated.^{3,j,k}

Safety and tolerability were consistent across all patients in the study and across other nipocalimab studies.^{7,8,9} The overall incidence of adverse events (AEs) was 84% in both the IMAAVY and the placebo arms and serious adverse events (SAEs) were 9% in the IMAAVY arm compared to 14% in the placebo arm.^{7,k}

Ongoing evidence generation in gMG will also be highlighted, including:

- Innovative PETUNIA study design: PETUNIA is designed to generate real-world safety data on pregnancy, maternal, and infant outcomes following exposure to IMAAVY during pregnancy.⁴ By leveraging prospective and retrospective reports the study aims to capture more detailed information on outcomes in this setting, helping to expand the evidence base beyond the traditional post-marketing safety monitoring requirements and support clinical decision-making in an area where current evidence is limited.^{4,c}

"People living with generalized myasthenia gravis often face unpredictable symptoms that can interfere with everyday life, underscoring the need for continued innovation grounded in disease biology," said David Lee, M.D., Ph.D., Global Immunology Therapeutic Area Head, Johnson & Johnson. "At Johnson & Johnson, we are committed to advancing research in autoantibody diseases to better understand the role of IMAAVY, an FcRn blocker designed to

help address the underlying cause of generalized myasthenia gravis, while preserving humoral immune function. We are continuing to explore the potential of IMAAVY in supporting sustained disease control across key moments in patients' lives."

The full list of accepted Johnson & Johnson abstracts can be found **HERE**.

IMAAVY is approved for adult and 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).^{10,11}

Editor's Notes:

- a. Anti-AChR+= anti-acetylcholine receptor positive antibody.
- b. Anti-MuSK+= anti-muscle specific tyrosine kinase positive antibody.
- c. Pregnancy Enhanced Tracking with Neonatal and Infant Assessment (PETUNIA) is a post-marketing FDA requirement.
- d. Dr. Carlo Antozzi has provided consulting, advisory and speaking services to Johnson & Johnson. He has not been paid for any media work.
- e. 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.¹²
- f. The proportion of patients achieving a meaningful clinical improvement [MCI] is defined as a ≥ 2 -point improvement in MG-ADL score at Week 24.^{1,2}
- g. At Week 24, patients diagnosed within five years who were treated with IMAAVY plus standard of care (SOC) achieved greater reductions in MG-ADL scores from baseline compared with placebo plus SOC (mean [SD]: -4.9 [2.88] vs -2.7 [2.46]; difference: -2.22 [standard error (SE): 0.76]; $p=0.005$).¹
- h. This is based on QMG (Quantitative Myasthenia Gravis) score which is a 13-item assessment by a clinician that quantifies MG disease severity through muscle weakness. The total QMG score ranges from 0 to 39, where higher scores indicated greater disease severity.¹²
- i. At Week 24, patients with MG-ADL scores lower than 9 treated with IMAAVY plus SOC achieved greater reductions in MG-ADL scores from baseline compared with placebo plus SOC (mean [SD]: -4.5 [2.64] vs -2.3 [2.37]; difference: -2.23 [SE: 0.588]; $p<0.001$). Additionally, QMG reductions were also greater with IMAAVY plus SOC from baseline compared to placebo plus SOC (mean [SD]: -5.2 [4.45] vs -1.9 [3.69]; difference: -3.38 [SE:0.986]; $p=0.001$).²
- j. Among patients who experienced an infection/infestation, the median (IQR) change from pre- to post-infection in MG-ADL scores was 0.0 (-1.0 to 1.0) with IMAAVY versus 1.0 (0.0 to 2.0) with placebo; in QMG scores, the median (IQR) change was 0.0 (-1.0 to 2.0) versus 1.0 (-1.0 to 1.0), respectively.³ Overall, infections/infestations were reported in 42.9% of patients in the IMAAVY group (71 events) and 41.8% in the placebo group (59 events).³

k. IMAAVY may increase the risk of infection, including serious infections. It is recommended to delay treatment in patients with active infection until resolution.¹⁰

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.^{13,14} The disease impacts an estimated 700,000 people worldwide.¹⁵ 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.¹⁵ Roughly 50% of individuals diagnosed with MG are women, and about one in five of those women are of child-bearing potential.^{16,17,18} Approximately 10 to 15% of new cases of MG are diagnosed in pediatric patients 12-17 years of age.^{17,19,20,21} 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.^{22,23,24}

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).^{25,26,27,28,29,30} This is characterized by severe muscle weakness and difficulties in speech and swallowing.^{25,26,27,28,29} Approximately 100,000 individuals in the U.S. are living with gMG.³¹ Vulnerable gMG populations, such as pediatric patients, have more limited therapeutic options.³²

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.^{33,34,35} 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.^{34,35} 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. Baseline demographics were balanced across arms (77 nipocalimab, 76 placebo).³⁵ 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.³⁴ A key secondary endpoint included change in Quantitative Myasthenia Gravis (QMG) score.³⁴ Long-term safety and efficacy were further assessed in an ongoing open-label extension (OLE) phase.

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 key immune functions.^{36,37,38} 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.¹⁰

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.^{34,39,40,41,42,43,44,45,46,47}

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 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

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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Janssen Biotech, Inc. is a Johnson & Johnson company.

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.

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