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NEWS RELEASE

# IMAAVY® (nipocalimab-aahu) shows over two years of sustained disease control in a broad population with generalized myasthenia gravis (gMG)

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Through 120 weeks of follow-up, IMAAVY delivered sustained clinical improvements and reductions in total IgG in antibody-positive adult patients including anti-AChR+ and anti-MuSK+

Patients achieving sustained minimal symptom expression (MSE) experienced greater improvements in quality of life than those with transient MSE in a post-hoc analysis of the Phase 3 study

EPIC, the first head-to-head study of IMAAVY versus another FcRn blocker in generalized myasthenia gravis, is now enrolling participants

HORSHAM, Pa., April 22, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new data from the Phase 3 Vivacity-MG3 study and ongoing open label extension (OLE) in a broad population of antibody-positive (including anti-AChR+[a] and anti-MuSK+[b]) adults with generalized myasthenia gravis (gMG) reinforcing the efficacy, sustained disease control and proven safety profile of IMAAVY® (nipocalimab-aahu). These data are among the seven abstracts Johnson & Johnson is presenting at the American Academy of Neurology (AAN) 2026 Meeting in Chicago, Illinois.

"For people living with gMG, consistent and durable symptom control is the central goal of treatment," said Constantine Farmakidis, MD, Associate Professor of Neurology at the University of Kansas Medical Center[c]. "These long-term results, now extending to beyond two years, provide further evidence that disease control, as initially observed in the nipocalimab Phase 3 pivotal study, can be sustained, and add to the body of evidence that may help guide clinical decision-making."

Sustained disease control is a key treatment objective in gMG, as long-term maintenance of low disease activity can help prevent exacerbations, reduce treatment burden and support meaningful function outcomes.[i] In addition, new post-hoc analyses explore the clinical relevance of sustained minimal symptom expression (MSE), an emerging patient-centric treatment goal that reflects minimal day-to-day disease impact for people living with gMG.[ii]

## Long-Term Data from OLE Phase[iii]

After the 24-week double-blind phase of the study, patients entered the ongoing OLE phase, with the latest results reflecting a total of 120 weeks of observation – among the longest follow-up periods reported for any FcRn blocker study in gMG. At 96 weeks in the OLE, IMAAVY demonstrated:

- Sustained improvements in MG-ADL[d] and QMG[e] scores over time, with mean reductions of 6.47[f] points on the total MG-ADL and 5.97[f] points on the total QMG scales – measures of MG symptom impact on daily living and muscle strength.
- Half of patients achieved MSE and nearly one-third (32%) achieved sustained MSE for at least 8 weeks on IMAAVY treatment.
- Incremental reduction of corticosteroid use was also observed through the OLE, with 57% of patients reaching low doses of ≤10 or ≤5 mg/day.
- Greater than 64%[f] reduction in total immunoglobulin G (IgG), including pathogenic IgG autoantibodies, the underlying driver of disease.

## Minimal Symptom Expression Data from Double-Blind Phase[iv]

A new post-hoc analysis from the 24-week double-blind portion of the study evaluated the impact of sustained MSE on quality of life (based on MG-QoL-15r[g] measure):

- Adults who received IMAAVY plus standard of care (SOC)[h] were four times more likely to reach sustained MSE, defined as achieving an MG-ADL score of 0 or 1 and maintaining it for at least 8 weeks, compared to those randomized to placebo.
- Patients who reached this level and sustainment of symptom control had the largest gains in day-to-day quality of life, compared with those with improvements that were not similarly sustained, or among those who did not attain MSE.

"As demonstrated in our pivotal trial, IMAAVY was shown to deliver sustained disease control in a broad population of people living with gMG, helping to address a critical unmet need," said Chris Gasink, MD, Vice President, Medical Affairs, Autoantibody & Gastroenterology, Johnson & Johnson. "These data reinforce our confidence in IMAAVY and our commitment to delivering treatments that can help more people living with gMG achieve meaningful, lasting

disease control."

Additionally, Johnson & Johnson previously **announced** plans to initiate EPIC in 2025, the first open-label study designed to compare FcRn blockers in adults with gMG who have never received an FcRn blocker. **The study**, comparing the efficacy of IMAAVY versus efgartigimod, is now enrolling participants.

For a full list of all Johnson & Johnson data being presented at AAN 2026 visit:
**https://www.jnj.com/innovativemedicine/neuroscience/myasthenia-gravis.**

## Editor's Notes:

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a. AChR+ = anti-acetylcholine receptor positive antibody
b. MUsK+ = anti-muscle specific tyrosine kinase positive antibody
c. Constantine Farmakidis, MD, has provided consulting, advisory, and speaking services to Johnson & Johnson. He has not been paid for any media work.
d. 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.[v]
e. 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.[vi]
f. Results reflect patients receiving IMAAVY and SOC throughout both the 24-week double-blind phase and OLE phase of the study.
g. As measured by MG-QoL-15r (Myasthenia Gravis Quality of Life 15-item Scale – Revised), a scale designed to assess important aspects of the patient's experience related to MG.[vii]
h. Standard of care was defined as a stable dose of current gMG treatment, including acetylcholinesterase inhibitors, glucocorticosteroids or immunosupressants (je, azathioprine, mycophenolate mofetil or mycophenolic acid, methotrexate, ciclosporin, tacrolimus, or cyclophosphamide).[viii]

## 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.[ix,x,xi] The disease impacts an estimated 700,000 people worldwide.[vii] 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.[xii] Roughly 50 percent of individuals diagnosed with MG are women, and about one in five of those women are of child-bearing potential.[xiii,xiv,xv] Approximately 10 to 15% of new cases of MG are diagnosed in pediatric patients 12-17 years of age.[xvi,xvii,xviii] 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.[xix,xx,xxi]

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). This is characterized by severe muscle weakness and difficulties in speech and swallowing.[xxii,xxiii,xxiv,xxv,xxvi] Approximately 100,000 individuals in the U.S. are living with gMG.[xxvii] Vulnerable gMG populations, such as pediatric patients, have more limited therapeutic options.[xxviii]

## 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.[xxix,xxx] 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.[xxvii] Baseline demographics were balanced across arms (77 nipocalimab, 76 placebo).[xxvii] 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.[xxvii] A key secondary endpoint included change in Quantitative Myasthenia Gravis (QMG) score. Long-term safety and efficacy were further assessed in an ongoing open-label extension (OLE) phase.[xxviii]

## ABOUT IMAAVY (nipocalimab-aahu)

IMAAVY is an immunoselective treatment designed to target, bind with high affinity, and block FcRn, reducing circulating IgG antibodies that drive disease while also preserving key 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.[xxxi]

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.[xxxii,xxxiii,xxxiv,xxxv,xxxvi,xxxvii,xxxviii,xxxix,xl]

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 HDFN in October 2019 and FNAIT in April 2025
- 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, 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

The legal manufacturer for IMAAVY is Janssen Biotech, Inc.

## 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:

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- 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:

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- 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.

cp-509746v1

## 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** 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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