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NEWS RELEASE

IMAAVY™ (nipocalimab-aahu) showed greater sustained disease control versus approved FcRn blockers for generalized myasthenia gravis (gMG) at multiple timepoints over 24 weeks in newly published indirect treatment comparison (ITC)

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The ITC compared all published Phase 3 data of these treatments, leveraging longitudinal results, and findings reinforce the importance of consistent, sustained disease control in managing a chronic autoantibody disease like gMG

IMAAVY, an FcRn blocker, received U.S. FDA approval earlier this year for the broadest population of individuals living with gMG, including anti-AChR and anti-MuSK antibody positive adults and pediatric gMG patients aged 12 and older

SPRING HOUSE, Pa., June 23, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new data from an indirect treatment comparison (ITC) that showed consistent and sustained disease control with IMAAVY™ (nipocalimab-aahu) versus other approved FcRn blockers in adults with generalized myasthenia gravis (gMG). These data, featured at the European Academy of Neurology (EAN) 2025 Congress in Helsinki, Finland, are among the 11 abstracts Johnson & Johnson is presenting.

Based on the ITC, which included the pivotal Phase 3 Vivacity-MG3 study data, IMAAVY showed comparable onset of symptom relief at Week 1 and showed consistent and sustained disease control with greater or statistically significant improvement of MG-ADL[a] scores versus the published Phase 3 data of other marketed FcRn blockers at several timepoints up to 24 weeks[b] of treatment.[1] Results were consistent across multiple ITC methods[c].

- Population-adjusted ITCs without a common control exhibited significantly greater mean improvements in MG-ADL scores favoring IMAAVY over other FcRn blockers, at Weeks 8-24[d] versus one comparator and at Weeks 10-14[d] versus another comparator.[1]
- In placebo-adjusted ITCs, IMAAVY was associated with numerically greater efficacy versus one treatment comparator at Weeks 8[e] and 18-24[e] and versus another at Weeks 10-14[e], with statistical significance at Weeks 10[f] and 12[f].[1]

"These analyses provide useful population-adjusted comparative data and add to the body of evidence supporting the use of IMAAVY for the treatment of gMG for certain patients," said Saiju Jacob, M.D., Professor, Department of Immunology and Immunotherapy at University of Birmingham, UK [f], "The significantly greater mean improvements on MG-ADL scores with IMAAVY reflect important new evidence of the ongoing need for sustained disease control in a chronic condition like gMG."

Unlike cyclic therapies that require clinical evaluation and symptom relapse prior to initiating subsequent treatment cycles, IMAAVY has a biweekly dosing regimen that may allow for a schedule that patients and healthcare providers can plan around.[2] These data provide insights about the predictability that IMAAVY may offer and potentially help clinical decision making when treating patients with gMG.

"At Johnson & Johnson, we recognize that for people living with gMG, the goal isn't just temporary relief, but rather sustained disease control. This analysis provides additional insights into the profile of IMAAVY and highlights its potential as a reliable treatment option for appropriate patients aged 12 and older living with gMG," said Katie Abouzahr, M.D., Vice President, Autoantibody Portfolio and Maternal Fetal Immunology Disease Area Leader, Johnson & Johnson Innovative Medicine. "As we continue to research the potential impact of IMAAVY and work with regulators worldwide, we are committed to helping patients with chronic, debilitating autoantibody conditions, like gMG."

ITCs are utilized by regulatory agencies, health technology assessment agencies and medical guideline committees to comparatively evaluate treatment options when there is no or limited availability of evidence from head-to-head clinical trials.[3] ITCs, however, cannot replace and should not be considered the same as head-to-head clinical trials.[3] Unanchored population-adjusted and placebo-anchored Bucher ITC methods were used in this analysis.[3] Unanchored population-adjusted indirect comparisons allow for adjustment of population differences using individual patient-level data from IMAAVY and aggregate data from other approved FcRn blockers.[3] Placebo-anchored Bucher ITCs evaluate a small number of treatments through a common comparator such as the trial placebo and use aggregate data from different trials.[3]

IMAAVY **is approved** in the U.S. for adult and pediatric patients (12 years of age and older) with anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive gMG. Johnson & Johnson also

submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) **seeking approval** of nipocalimab in gMG in September 2024.

Editor's notes:

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a. 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.[4]
b. There are no head-to-head data available for any FcRn blockers, and no claim of superiority can be made about any FcRn blockers in the absence of such head-to-head trial data.
c. The ITC did not evaluate safety among the FcRn blocker agents.
d. In unanchored population-adjusted indirect comparison, IMAAVY versus one treatment at Week 8 had a mean difference of -2.36 [(95% confidence interval [CI]: -3.56, -1.16); P=0.001]; this trend continued up to Week 24 (P<0.05). For another comparator, at Week 10 IMAAVY had a mean difference of –2.38 at one comparator dose [(95% CI: -3.57, -1.18); P<0.001] and a mean difference of -3.14 with a different comparator dose [(95% CI: -4.15, -2.14); P<0.001]; this trend continued up to Week 14 (P<0.001).
e. In placebo-anchored indirect comparison, MG-ADL change from baseline (CFB) was greater at Week 8 by -1.24 versus one treatment comparator (95% CI: -2.78, 0.30), at Week 18 by -1.13 (95% CI: -2.77, 0.50), at Week 20 by -1.44 (95% CI: -3.21, -0.33), at Week 22 by -1.79 (95% CI: -4.16, 0.59), and at Week 24 by -2.89 (95% CI: -5.67, -0.12).
f. In placebo-anchored indirect comparison, treatment with IMAAVY demonstrated a greater MG-ADL CFB versus a comparator dose at Week 10 (mean CFB=-1.19, 95% CI: -2.75, 0.37), Week 12 (mean CFB= -1.41, 95% CI: -2.94, 0.12) and Week 14 (mean CFB= -1.01, 95% CI: -2.51, 0.49).
   • Similar trends were observed for IMAAVY versus a different comparator dose at Week 10 (mean CFB= -2.16, 95% CI: -3.58, -0.73), Week 12 (mean CFB= -1.99, 95% CI: -3.53, -0.45) and Week 14 (mean CFB= -1.12, 95% CI: -2.55, 0.31).
g. Saiju Jacob, 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.[5,6,7] The disease impacts an estimated 700,000 people worldwide.[5] 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.[8] Roughly 50 percent of individuals diagnosed with MG are women, and about one in five of those women are of child-bearing potential.[9,10,11] Approximately 10 to 15% of new cases of MG are diagnosed in pediatric patients 12-17 years of age.[12,13,14] 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.[15,16,17]

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.[18,19,20,21,22] Approximately 100,000 individuals in the U.S. are living with gMG.[23] Vulnerable gMG populations, such as pediatric patients, have more limited therapeutic options.[24]

ABOUT THE INDIRECT TREATMENT COMPARISON

Indirect treatment comparisons (ITCs) were conducted to compare efficacy onset using 1-week timepoint, and for consistency and sustained disease control, comparisons were conducted for multiple timepoints up to 24 weeks for one treatment comparator (up to 3-cycle duration) and up to 14 weeks for another treatment comparator (final visit data reported).[1] The data used in the analysis came from published registrational trials of IMAAVY and comparator FcRn blockers approved to treat gMG (efgartigimod and rozanolixizumab).[1] The differences in clinical trial design across FcRn blockers coupled with differences in background standard of care (SOC) required multiple indirect treatment comparison methods to be utilized.[1] Therefore, ITCs were conducted using unanchored population-adjusted indirect comparisons (with active treatment arm only and adjusting for cross-trial patient differences) and placebo-anchored (includes both active treatment and placebo arms) Bucher method. Differences <0 favored nipocalimab for all comparisons.[1] This ITC adheres to all governing standards and requirements as demanded by global health technology assessment agencies, journal review committees and regulatory authorities. The ITC was funded by Janssen Research & Development, LLC.[1]

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.[25,26] 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.[25] Baseline demographics were balanced across arms (77 nipocalimab, 76 placebo).[25] 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.[25] 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.[26]

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 in the U.S. for the treatment of gMG in adults and pediatric patients 12 years of age and older who are AChR or MuSK antibody positive.[2]

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.[28,29,30,31,32,32,33,34,35,36] 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 and FNAIT in April 2025

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:

- o a swollen face, lips, mouth, tongue, or throat
- o difficulty swallowing or breathing
- o itchy rash (hives)
- o 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:

- o headache
- o rash
- o nausea
- o fatigue
- o dizziness
- o chills
- o flu-like symptoms
- o 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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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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[2] IMAAVY™ U.S. Prescribing Information

[3] Nils Erik Gilhus, Saiju Jacob, Mahmoud Hashim, Suzy Van Sanden, Christopher Drudge, Anna Nero, Sumeet Singh, Kavita Gandhi, and Brian Hutton Network connectivity, between-study heterogeneity and timepoint challenges in generalized myasthenia gravis: a feasibility assessment of indirect treatment comparisons. (2025) Journal of Comparative Effectiveness Research. DOI: 10.57264/cer-2025-0009

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