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NEWS RELEASE

New nipocalimab data and real-world research at AAN 2025 highlight positive Phase 3 results and commitment to people living with generalized myasthenia gravis (gMG)

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Oral presentation features new data from the 24-week pivotal Vivacity-MG3 study which show sustained disease control through treatment with nipocalimab on the clinician-assessed QMG[a] score in antibody positive adult patients: anti-AChR+, anti-MuSK+, anti-LRP4+

Nipocalimab data demonstrate longer-term sustained disease control as measured by MG-ADL[b] and QMG scores from the ongoing open-label extension (OLE) of the Vivacity-MG3 study

Johnson & Johnson filed a Biologics License Application (BLA) for nipocalimab in August 2024 and was granted U.S. FDA Priority Review for the treatment of gMG

Real-world studies highlight the unmet need of patients living with gMG, including those who are pregnant or receiving steroids

SPRING HOUSE, Pa., March 26, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) announced today that 12 abstracts, including two oral presentations, highlighting the Company's innovative autoantibody disease research and the potential of nipocalimab to provide long-term sustained disease control in the treatment of generalized myasthenia gravis (gMG), will be presented at the 2025 American Academy of Neurology (AAN) Annual Meeting from April 5 – 9 in San Diego, California.

Oral and poster presentations include data from the pivotal Phase 3 Vivacity-MG3 study of nipocalimab in

gMG, which was included in the U.S. Biologics License Application (BLA) for nipocalimab:

- Data evaluating nipocalimab using the clinician-administered QMG[a] assessment score demonstrated significant improvement in muscle strength. (**Oral #001**)
- Results from the ongoing open-label extension (OLE) study evaluating long-term efficacy and safety of nipocalimab show sustained disease control with nipocalimab in a broad population of antibody-positive gMG adult patients. (**Poster #11-022**)

Real-world evidence and unmet needs in myasthenia gravis (MG) treatment

- Real-world data showcases the unmet needs in treating gMG during pregnancy, and an urgency for further research on treatment options for women with MG who might become pregnant. (**Oral #005**) Nipocalimab continues to be the only investigational treatment with both **published** data and ongoing Phase 3 studies in pregnant women at risk of alloantibody conditions of pregnancy, including hemolytic disease of the fetus and newborn (HDFN), and fetal neonatal alloimmune thrombocytopenia (FNAIT).[1,2,3]
- Poster presentations highlight data from two studies examining the association of oral corticosteroid (OCS) exposure in MG, emphasizing the need for additional targeted treatment options with demonstrated safety profiles to minimize the well-known risks of oral corticosteroids. (Posters **#11-029** and **#8-007**)
- Findings from a real-world study of MG serostatus testing show variation in MG antibody testing in current clinical practice, uncovering infrequent MuSK and LRP4 testing among antibody negative patients. The study found a socioeconomic correlation to lack of further diagnostic testing which highlights an opportunity in care and can inform more targeted treatment plans. (**Poster #11-030**)

Patient-reported data & disease burden:

- A poster presentation will showcase patient-reported insights on factors contributing to MG exacerbations and symptom worsening (**Poster #11-010**):
    - Findings suggest that many individuals currently living with MG in the U.S. reported uncontrolled disease. Important risk factors identified for exacerbation or symptom worsening included living alone, generalized MG symptomology, and comorbid anxiety/depression.

These findings underscore the ongoing need for additional approved immunoselective therapies that are effective with demonstrated safety profiles for people living with gMG.

"We're excited to share our latest research in gMG, reinforcing our commitment to advancing innovation in the autoantibody disease space. These presentations highlight our dedication to helping address critical unmet needs and improving outcomes for a broad population of patients through our pathway-based approach to research and development," said Katie Abouzahr, M.D., Vice President, Autoantibody and Maternal Fetal Immunology Disease

Area Leader, Johnson & Johnson Innovative Medicine. "We look forward to engaging with the medical and patient community at AAN and continuing important scientific exchange that drive progress in patient care."

The full list of accepted Johnson & Johnson abstracts is below.

Data presentation highlights: AAN – April 5-9

Presenter/Presentation Time (PT) Poster Number	Abstract Name
Oral Session	
Session 34 #001 Date: Wednesday, April 9 Presentation Time: 1:00 PM	Ph3 VIVACITY QMG: Efficacy of Nipocalimab, a Novel Neonatal Fragment Crystallizable Receptor Blocker, as Measured Using Quantitative Myasthenia Gravis Assessment: Findings from the Phase 3 Placebo-controlled Vivacity-MG3 Study
Session 34 #005 Date: Wednesday, April 9 Presentation Time: 1:48 PM	Komodo: Real-world Interaction between Pregnancy and Generalized Myasthenia Gravis
Poster Session	
Session 7 #11-022 Date: Monday, April 7 Session Time: 5:00 PM – 6:00 PM	Ph3 VIVACITY OLE: Long-Term Safety and Efficacy of Nipocalimab in Generalized Myasthenia Gravis: Vivacity-MG3 Open-Label Extension Phase Results
Session 6 #11-027 Date: Monday, April 7 Session Time: 11:45 AM –12:45 PM	Komodo: Real-world Treatment Patterns Among Patients with Generalized Myasthenia Gravis
Session 9 #11-034 Date: Tuesday, April 8 Presentation Time: 11:45 AM – 12:45 PM	HCRU: Economic Burden of Myasthenia Gravis Exacerbation and Crisis from US Payer Perspective
Session 7 #11-029 Date: Monday, April 7 Presentation Time: 5:00 PM – 6:00 PM	OCS SWIMM: Long-term Use of Oral Corticosteroids and Overall Survival Among Patients with Myasthenia Gravis: A Nationwide Population-based Study
Session 1 #11-010 Date: Saturday, April 5 Presentation Time: 11:45 AM – 12:45 PM	MGFA Patient Registry: Identifying Risk Factors for Exacerbation and Symptom Worsening—a Retrospective Cohort Study of Patients with Myasthenia Gravis in the United States
Session 8 #11-032 Date: Tuesday, April 8 Presentation Time: 8:00 AM – 9:00 AM	Measures that Matter: Design of a Digital Solution to Improve Myasthenia Gravis Patient Symptom Tracking in Routine Clinical Care
Session 6 #11-030 Date: Monday, April 7 Presentation Time: 11:45 AM – 12:45 PM	Health Analytics: Serostatus Testing Patterns Among Individuals with Myasthenia Gravis: Implications for Patient Care
Session 1 #11-022 Date: Saturday, April 5 Presentation Time: 11:45 AM – 12:45 PM	ADELPHI DSP 2: Treatment-related Characteristics Among Younger Women with Generalized Myasthenia Gravis
Session 4 #8-007 Date: Sunday, April 6 Presentation Time: 5:00 PM – 6:00 PM	Optum: Complications in Patients with Myasthenia Gravis Treated with Oral Corticosteroids
Session 4 #8-001 Date: Sunday, April 6 Presentation Time: 5:00 PM – 6:00 PM	Optum: Healthcare Costs in a Commercially Insured Population of Patients with Generalized Myasthenia Gravis and Related Clinical Events

Editor's notes:

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a. 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.
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.

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] or anti-low density lipoprotein-related protein 4 [LRP4]), which target proteins at the neuromuscular junction and can block or disrupt normal signaling from nerves to muscles, thus impairing or preventing muscle contraction.[4,5,6] The disease impacts an estimated 700,000 people worldwide.[4] 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.[7] Roughly 50 percent of individuals diagnosed with MG are women, and about one in five of those women are of child-bearing potential.[8,9,10]Approximately 10 to 15% of new cases of MG are diagnosed in adolescents (12 – 17 years of age).[11,12,13] 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.[14,15,16]

Initial disease manifestations are usually ocular 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.[17,18,19,20,21] Approximately 100,000 individuals in the U.S. are living with gMG.[22] Vulnerable gMG populations, such as pediatric patients, have more limited therapeutic options.[23] Currently, SOC treatments for adolescents with gMG are extrapolated from adult trials.[13] Other than symptomatic treatments, there are no approved FcRn blockers for adolescents with gMG in the United States.[13]

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.[24,25] 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.[24] Baseline demographics were balanced across arms (77 nipocalimab, 76 placebo).[24] The primary endpoint of the study was mean change in MG-ADL[b] score from baseline over Weeks 22, 23 and 24 in antibody positive patients. 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.[25]

ABOUT NIPOCALIMAB

Nipocalimab is an investigational monoclonal antibody, designed to bind with high affinity to block FcRn and reduce levels of circulating immunoglobulin G (IgG) antibodies potentially without impact on other immune functions. This includes autoantibodies and alloantibodies that underlie multiple conditions across three key segments in the autoantibody space including Rare Autoantibody diseases, Maternal Fetal diseases mediated by maternal alloantibodies and Rheumatic diseases.[3,25,26,27,28,29,30,31,32] Blockade of IgG binding to FcRn in the placenta is also believed to limit transplacental transfer of maternal alloantibodies to the fetus.[33,34]

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 HDFN and warm autoimmune hemolytic anemia (wAIHA) in July 2019, gMG in December 2021, 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

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 nipocalimab. 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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