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NEWS RELEASE

Johnson & Johnson highlights new data that showcase the strength of nipocalimab, demonstrating long-term sustained disease control in adults living with generalized myasthenia gravis (gMG)

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New compelling results demonstrate 18 months of both sustained reduction in immunoglobulin G antibodies and sustained improvement in gMG symptoms in pivotal Vivacity-MG3 study and open-label extension phase

Up to 128 weeks and 180 patient years of follow-up in the open-label extension[a] confirm a safety profile consistent with the Phase 3 Vivacity-MG3 study

45% of the patients receiving steroids at open-label extension baseline were able to decrease or discontinue their steroid use

Additionally, the nipocalimab plus standard of care (SOC) group demonstrated four times greater odds of improving and maintaining the strength and function of different muscle groups as measured by QMG[b] response versus placebo plus SOC in the 24-week double blind phase of the study

SPRING HOUSE, Pa., April 8, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced results from additional analyses of the Phase 3 Vivacity-MG3 double-blind study and the ongoing open-label extension[a] (OLE), evaluating the long-term efficacy and safety of investigational nipocalimab in a broad population of antibody-positive (anti-AChR+, anti-MuSK+, anti-LRP4+) adults with generalized myasthenia gravis (gMG).[1,2] Patients treated with nipocalimab plus standard of care (SOC) maintained improvements in their MG-ADL[c] and QMG[b] scores over 84

weeks with sustained reductions in total immunoglobulin G (IgG).[1] These data are included in a presentation (Session 7 #022) and are among **12 abstracts** that Johnson & Johnson will present at the American Academy of Neurology (AAN) 2025 Meeting in San Diego, California, which includes an oral presentation on QMG score improvements from the double-blind phase of the Phase 3 Vivacity-MG3 study.

"The sustained disease control seen over 84 weeks for nipocalimab is a key result given the chronic course of generalized MG and the significant burden on people living with this condition," said Constantine Farmakidis M.D., Associate Professor of Neurology at University of Kansas Medical Center[d]. "Overall, I am encouraged by these results that show improvement in disease control as measured by the MG-ADL and QMG scores across a broad population seropositive for AChR, MuSK, or LRP4 autoantibodies."

Nipocalimab demonstrated a mean change in MG-ADL of -5.64 ($p<0.001$) from the double-blind baseline after 60 weeks in the OLE for study participants receiving nipocalimab and SOC, and -6.01 ($p<0.001$) mean change for study participants who transitioned from placebo and SOC to nipocalimab and SOC.[1] In the antibody-positive population, 45% of patients receiving steroids at the OLE baseline were able to decrease or discontinue steroids at the time of this data cut by more than half of the baseline dose.[1] Among these patients, the mean dose of prednisone decreased from 23 to 10 mg per day.[1] Nipocalimab had a consistent and tolerable safety profile throughout the OLE phase.[1]

Additional findings from the Phase 3 Vivacity-MG3 double-blind study indicate that patients treated with nipocalimab plus SOC achieved statistically significant improvements in their QMG score by -4.9 versus placebo plus SOC ($p<0.001$) over weeks 22 and 24.[2] Patients in the nipocalimab plus SOC treatment group were four times more likely to sustain symptom improvement at 20 weeks compared to the placebo plus SOC group, as measured by a three or greater point improvement on the QMG score.[2] Results show significantly more patients treated with nipocalimab (36.4%,) versus placebo (10.5%, $p<0.001$) spent greater than 75% of study duration demonstrating improvements in the QMG score.[2] A reduction of more than three points in the QMG score indicates a decrease in the severity of the patient's symptoms as a result of improvements in muscle strength, allowing patients to carry out important daily activities such as swallowing and chewing.[3,4]

"People living with generalized MG around the world endure daily challenges, such as difficulties swallowing, impaired speech and muscle weakness. They deserve additional, effective treatment options that help address these challenges and provide sustained disease control and stability over time," said Katie Abouzahr, M.D., Vice President, Autoantibody Portfolio and Maternal Fetal Immunology Disease Area Leader, Johnson & Johnson Innovative Medicine. "These positive data underscore our commitment to helping develop potential innovative therapeutic options for patients living with autoantibody diseases, including gMG."

Editor's notes:

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a. The open-label extension (OLE) interim analysis includes 60 weeks of open-label data, totalling 84 weeks for nipocalimab-treated participants, including 24 weeks from the treatment group of the double-blind phase. Some patients have follow-up data extending to 128 weeks.[1]
b. 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.[3]
c. 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.[3]
d. Dr. Constantine Farmakidis 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] 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.[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 adolescents (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 ocular, but 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 of the skeletal muscles 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] Currently, SOC treatments for adolescents with gMG are extrapolated from adult trials.[14] Other than symptomatic treatments, there are no approved FcRn blockers for adolescents with gMG in the United States.[14]

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.[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 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.[26]

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.[26,27,28,29,30,31,32,33,34] Blockade of IgG binding to FcRn in the placenta is also believed to limit transplacental transfer of maternal alloantibodies to the fetus.[35,36]

The U.S. FDA and 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 and fetal 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

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.

[1] Antozzi, C et al., Long-Term Safety and Efficacy of Nipocalimab in Generalized Myasthenia Gravis: Vivacity-MG3 Open-Label Extension Phase Results. Abstract #022 for poster presentation at 2025 American Academy of Neurology Congress. April 2025.
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