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NEWS RELEASE

Johnson & Johnson seeks first approval of nipocalimab to treat broadest population living with antibody positive generalized myasthenia gravis

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Marks first FDA submission for nipocalimab, an investigational treatment that binds with high affinity and specificity to block FcRn and reduce levels of autoantibodies

Filing based on the Phase 3 Vivacity-MG3 program, the first-and-only study results in the class demonstrating sustained disease control over 24 weeks in antibody positive adult patients: anti-AChR+, anti-MuSK+, anti-LRP4+

SPRING HOUSE, Pa., Aug. 29, 2024 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) seeking the first approval of nipocalimab globally for the treatment of people living with generalized myasthenia gravis (gMG).

The application included data from the Phase 3 Vivacity-MG3 study which showed that outcomes for a broad population of antibody positive participants who received nipocalimab plus standard of care (SOC) were superior compared to those who received placebo plus SOC. The primary endpoint of the study measured improvement in the MG-ADL[a] score from baseline over 24 weeks and study participants included anti-AChR+, anti-MuSK+, and anti-LRP4+[b] antibody positive adults, which account for approximately 95 percent of the gMG patient population, making Vivacity-MG3 the first-and-only study to demonstrate sustained disease control in these subtypes.[1,2] Safety and tolerability were consistent with other nipocalimab studies.[3,4,5]

"We are encouraged by the potential of nipocalimab to provide sustained disease control for people living with generalized myasthenia gravis, a chronic, life-long disease," said Bill Martin, Ph.D., Global Therapeutic Area Head, Neuroscience, Johnson & Johnson Innovative Medicine. "The filing for approval of nipocalimab represents an

important step forward as Johnson & Johnson continues to push the boundaries of research to develop innovative solutions to treat autoantibody-driven diseases, building on decades of expertise in neuroscience and immunology. We look forward to working with the FDA in their review of the data supporting the submission."

Nipocalimab is the **first-and-only FcRn blocker** to demonstrate sustained disease control measured by improvement in MG-ADL when added to background SOC compared with placebo plus SOC over a period of six months of consistent dosing (every other week)[c], which is the longest period of controlled safety and efficacy assessment of an FcRn blocker in gMG.

Earlier this year at the American Academy of Neurology Annual Meeting, Johnson & Johnson **presented data** focused on the molecular properties of nipocalimab. Characteristics such as its high binding affinity and specificity to the immunoglobulin G (IgG) binding site of FcRn have the potential to differentiate nipocalimab in the FcRn blocker class of treatments.[6] These properties, along with the dosing regimen chosen for the study, are thought to lower IgG, including IgG autoantibodies in diseases such as gMG and other autoantibody-driven diseases.[7]

Editor's notes:

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.

b. Positive patients include anti-acetylcholine receptor positive antibody (AChR+), anti-muscle specific tyrosine kinase positive antibody (MuSK+) and/or anti-low density lipoprotein receptor-related protein 4 positive antibody (LRP4+).

c. Patients who received nipocalimab plus current SOC had a mean change of -4.70 [standard error (SE) 0.329]. Patients on placebo plus current SOC had a mean change of -3.25 (SE 0.335); difference of least-squares (LS) means -1.45 [0.470]; P=0.002.

About Generalized Myasthenia Gravis (gMG)

Myasthenia gravis (MG) is an autoantibody disease in which autoantibodies target proteins at the neuromuscular junction, disrupt neuromuscular signaling, and impair or prevent muscle contraction.[8] In MG, the immune system mistakenly attacks proteins at the neuromuscular junction by producing antibodies (e.g., anti-acetylcholine receptor [AChR], anti-muscle-specific tyrosine kinase [MuSK] or anti-low density lipoprotein-related protein 4 [LRP4]) that can block or disrupt normal functioning, preventing signals from transferring from nerves to muscles.[9] The disease impacts an estimated 700,000 people worldwide.[8] The disease affects both men and women and occurs across all

ages, racial and ethnic groups, but most frequently impacts young women and older men.[10] Roughly 50 percent of individuals diagnosed with MG are women, and about one in five of those women are of child-bearing potential.[11,12,13]

Initial disease manifestations are usually ocular but in 85 percent or more[14,15] cases, the disease generalizes (gMG), which is characterized by fluctuating weakness of the skeletal muscles leading to symptoms like limb weakness, drooping eyelids, double vision and difficulties with chewing, swallowing, speech, and breathing.[8,16,17] Approximately 100,000 individuals in the U.S. are living with gMG.[18] Although gMG may be managed with current conventional therapies, new therapies are needed for those who may not respond well enough to or tolerate these options.

About the Phase 3 Vivacity-MG3 Study

The Phase 3 Vivacity-MG3 study was specifically designed to measure sustained efficacy and safety with consistent dosing in this unpredictable chronic disease 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 which were antibody positive, enrolled in the 24-week double-blind placebo-controlled trial. 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). The primary endpoint of the study was mean change in MG-ADL[a] score from baseline over Weeks 22, 23 and 24 in antibody positive patients. A key secondary endpoint included change in Quantitative Myasthenia Gravis (QMG) score, which is a 13-item assessment by a clinician that quantifies MG disease severity. Long-term safety and efficacy were further assessed in an ongoing OLE phase.[19]

About Nipocalimab

Nipocalimab is an investigational monoclonal antibody, purposefully designed to bind with high affinity to block FcRn and reduce levels of circulating immunoglobulin G (IgG) antibodies, while preserving immune function without causing broad immunosuppression. 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 Prevalent Rheumatology.[19,20,21,22,23,24,25,26,27] Blockade of IgG binding to FcRn in the placenta is also believed to prevent transplacental transfer of maternal alloantibodies to the fetus.[28,29]

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 and fetal neonatal alloimmune thrombocytopenia (FNAIT) in March 2024 by the FDA
- 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 by the FDA
- U.S. FDA Breakthrough Therapy designation for HDFN in February 2024 by the FDA
- EU EMA Orphan medicinal product designation for HDFN in October 2019 by the EMA

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 Research & Development, LLC and Janssen Biotech, Inc. are both Johnson & Johnson companies.

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 Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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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Media contact:
Bridget Kimmel
Mobile: (215) 688-6033
bkimmel@its.jnj.com

Investor contact:
Raychel Kruper
investor-relations@its.jnj.com

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