News Release

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Janssen to Highlight Latest Research from Nipocalimab Clinical Development Program to Address Unmet Need in Myasthenia Gravis at AANEM 2023 Meeting

Data presentations reinforce potential for rapid, deep, and sustained efficacy with treatment and demonstrate how the unique immuno-selectivity of the compound may allow for greater targeting across a wide range of autoantibody-driven diseases

Titusville, N.J., October 16, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that 20 company-sponsored presentations from its nipocalimab and autoantibody diseases research program will be showcased at the 2023 American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Meeting from November 1-4 in Phoenix, Arizona.

Generalized myasthenia gravis (gMG) remains one of the autoantibody-driven diseases for which limited treatment options are available. These data underscore the potential of investigational nipocalimab in reducing the burden associated with autoantibody-driven diseases, while also helping to address the unmet treatment need that remains despite existing therapies.

"We are pleased to present the latest findings from our clinical development program for nipocalimab at the AANEM 2023 Meeting," said Bill Martin, Ph.D., Global Therapeutic Area Head, Neuroscience, Janssen Research & Development, LLC. "Nipocalimab is purposely designed to address the underlying cause of autoantibody-driven diseases through the rapid, deep, and sustained reduction of Immunoglobulin G (IgG), including pathogenic IgG."

The Company Data Presentations Include:

- **MGNation: A Real-World Study Capturing Patient, Healthcare Professional and Caregiver Perspectives**
  This innovative, non-interventional study seeks to understand the real-world treatment of patients with moderate to severe uncontrolled gMG and suboptimal response to standard of care treatments.

- **Evaluation of Complement Biomarkers After Treatment With Nipocalimab in Generalized Myasthenia Gravis**
  The purpose of this study is to evaluate whether nipocalimab treatment impacts complement activation by lowering anti-AchR antibody in the VIVACITY-MG Phase 2 Study.

- **Reduced Immunoglobulin G and Anti-Acetylcholine Receptor Antibodies Explain Nipocalimab Effect on Improved Myasthenia Gravis Activities of Daily Living Score in Generalized Myasthenia Gravis Patients**
  This analysis aims to quantify the relationship between IgG, anti-AChR antibodies and the clinical efficacy endpoint (Myasthenia Gravis Activities of Daily Living [MG-ADL] score) to understand if IgG or anti-AChR antibody titer reduction could account for nipocalimab effect on MG-ADL.

- **IgG Reduction Explains a Large Proportion of Clinical Efficacy in Generalized Myasthenia Gravis – A Model-Based Meta-Analysis of FcRn Inhibitors**
  This model-based meta-analysis of clinical data from four anti-FcRn treatments was used to explore IgG as a potential biomarker for the clinical endpoint, MG-ADL score, while also assessing the efficiency of clinical trials (size and duration) to reduce burden for patients with gMG.

A complete listing of company-sponsored abstracts is provided below. Abstracts can also be viewed on the AANEM Meeting 2023 website.

Poster #	Title
Oral 58	**MGNation: A Real-World Study Capturing Patient, Healthcare Professional and Caregiver Perspectives**
P18	**Partnering With Patients and Care Partners to Guide the Design of a Generalized Myasthenia Gravis Real-World Study**
P16	**Specific Attributes of Myasthenia Gravis Patients May Correlate With a Higher Burden of Depression and Anxiety: A Literature Review**
P110	**Long-Term Healthcare Resource Utilization and Costs Among Patients With Newly Diagnosed MG: A Swedish Nationwide Population-Based Study**
P114	**IgG Reduction Explains a Large Proportion of Clinical Efficacy in gMG – A Model-Based Meta-Analysis of FcRn Inhibitors**
P115	**Evaluation of Complement Biomarkers After Treatment With Nipocalimab in Generalized Myasthenia Gravis**
P147	**Reduced IgG and Anti-Acetylcholine Receptor Antibodies Explain Nipocalimab Effect on Improved MG Activities of Daily Living Score in gMG Patients**

P158	**Delayed Diagnosis Amongst gMG Patients: Results From a European Real-World Study**
P159	**Changing Priorities Among Physician Reported Reasons for Choice of Pharmacological gMG Treatments Across 5 European Countries**
P175	**Nipocalimab Dose Selection for Adult Patients With Generalized Myasthenia Gravis**
P198	**Identification of Myasthenia Gravis Exacerbations, Crises, and Symptom Burden Using Rules-Based Natural Language Processing Applied to Neurologist Clinical Notes**
P199	**Identification of Generalized Myasthenia Gravis and Antibody Status Using Rules-Based Natural Language Processing Applied to Neurologist Clinical Notes**
P200	**Real-World Characterization of Challenges Related to the Identification and Management of Myasthenia Gravis Crisis**
P219	**Cellular and In Vivo Preclinical Pharmacodynamics and Pharmacology of Nipocalimab, an Anti-FcRn Blocking Therapeutic Antibody**
P225	**A Phase 2/3 Placebo-Controlled, Parallel Group, Randomized Withdrawal Study to Evaluate the Efficacy and Safety of Nipocalimab for Adults With Chronic Inflammatory Demyelinating Polyneuropathy: the ARISE Study**
P242	**Real-World Insights Into Differing Clinical Presentation of Myasthenia Gravis Patients on Pharmacological Treatment in the USA and Five European Countries**
P243	**Characteristics of Progressive Myasthenia Gravis Patients in Real-World Practice in the USA and Five European Countries**
P244	**Healthcare Utilization and Costs of Adults With Myasthenia Gravis and Common Comorbidity or Disease Activity Profiles**
P256	**Retrospective Study of Select Adverse Events of Special Interest Associated With Corticosteroid Use in Myasthenia Gravis**
P257	**Design of Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Nipocalimab in Participants With Active Idiopathic Inflammatory Myopathies**

About Nipocalimab

Nipocalimab is an investigational, high affinity, fully human, aglycosylated, effectorless, monoclonal antibody that is believed to selectively block the Fc receptor (FcRn) to reduce levels of circulating immunoglobulin G (IgG) antibodies, including autoantibodies and alloantibodies that underlie multiple conditions. Nipocalimab is being studied in all three segments of autoantibody-driven disease: rare autoantibody diseases (e.g., generalized myasthenia gravis in adults and children, chronic inflammatory demyelinating polyneuropathy, warm autoimmune hemolytic anemia, and idiopathic inflammatory myopathies); maternal fetal diseases mediated by maternal autoantibodies – also known as alloantibodies (e.g., HDFN); and prevalent rheumatologic diseases (e.g., rheumatoid arthritis, Sjögren's syndrome, and systemic lupus erythematosus).[1,2-10] Blockade of FcRn by nipocalimab has the potential to reduce overall autoantibody levels while maintaining immune function. FcRn blockade is also believed to prevent placental transfer of maternal alloantibodies to the fetus.[1,11]

About Myasthenia Gravis (MG)

Myasthenia gravis (MG) is an autoantibody disease where autoantibodies target proteins at the neuromuscular junction, disrupt neuromuscular signaling, and impair or prevent muscle contraction. The disease impacts an estimated 700,000 people worldwide with 85% of these patients experiencing the more extensive form of the disease, generalized myasthenia gravis (gMG).[12] In MG, the immune system mistakenly attacks muscle receptors by producing anti-receptor antibodies (most commonly anti-acetylcholine receptor [AChR] or anti-muscle-specific kinase [MuSK] antibodies) that can block or destroy these muscle receptors, preventing signals from transferring from nerves to muscles. In gMG, the blocking leads to symptoms such as limb weakness, drooping eyelids, double vision, as well as difficulties with chewing, swallowing, speech, and breathing. Although gMG may be managed with current therapies, research is needed to develop new treatments for those who may not respond well enough to or tolerate current therapies.

VIVACITY-MG Study Design

VIVACITY-MG is a Phase 2, multicenter, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, efficacy, pharmacokinetics, pharmacodynamics, and immunogenicity of nipocalimab administered to adults with gMG. Sixty-eight anti-receptor antibody-positive patients were randomized 1:1:1:1:1 to 4 treatment groups or a placebo group. To maintain study blinding, all patients received an intravenous infusion (either nipocalimab or placebo) every other week for a total of 5 infusions during the 8-week treatment period. After completion of the follow-up period, patients could enroll in a separate open-label extension study and receive treatment with nipocalimab. VIVACITY-MG Phase 3 clinical trials are ongoing.

Janssen gained full global rights to nipocalimab through the acquisition of Momenta Pharmaceuticals, Inc., a company that discovers and develops novel therapies for immune-mediated diseases, in August 2020.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism & Retina, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at Twitter.com/JNJInnovMed. Janssen Research & Development, LLC and Janssen Global Services, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding nipocalimab product development. 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 Global Services, LLC 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 ending January 1, 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. Neither Janssen Research Development, LLC, Janssen Global Services, LLC, 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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1. ClinicalTrials.gov. A Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of M281 Administered to Pregnant Women at High Risk for Early Onset Severe Hemolytic Disease of the Fetus and Newborn (HDFN). Identifier: NCT03842189. Available at: https://clinicaltrials.gov/ct2/show/NCT03842189. Accessed January 18, 2023.
2. ClinicalTrials.gov. Identifier: NCT05265273. Available at: https://clinicaltrials.gov/ct2/show/NCT05265273. Accessed January 18, 2023.
3. ClinicalTrials.gov. Identifier: NCT04951622. Available at: https://clinicaltrials.gov/ct2/show/NCT04951622. Accessed January 18, 2023.
4. ClinicalTrials.gov. Identifier: NCT05327114. Available at: https://clinicaltrials.gov/ct2/show/NCT05327114. Accessed January 18, 2023.
5. ClinicalTrials.gov. Identifier: NCT03842189. Available at: https://clinicaltrials.gov/ct2/show/NCT03842189. Accessed January 18, 2023.
6. ClinicalTrials.gov. Identifier: NCT04119050. Available at: https://clinicaltrials.gov/ct2/show/NCT04119050. Accessed January 18, 2023.
7. ClinicalTrials.gov. Identifier: NCT04968912. Available at: https://clinicaltrials.gov/ct2/show/NCT04968912. Accessed January 18, 2023.
8. ClinicalTrials.gov. Identifier: NCT04882878. Available at: https://clinicaltrials.gov/ct2/show/NCT04882878. Accessed January 18, 2023.
9. ClinicalTrials.gov. Identifier: NCT05379634. Available at: https://clinicaltrials.gov/ct2/show/NCT05379634. Accessed January 18, 2023.
10. ClinicalTrials.gov. Identifier: NCT04991753. Available at: https://clinicaltrials.gov/ct2/show/NCT04991753. Accessed January 18, 2023.
11. Roy S, Nanovskaya T, Patrikeeva S, et al. M281, an anti-FcRn antibody, inhibits IgG transfer in a human ex vivo placental perfusion model. *Am J Obstet Gynecol*. 2019;220(5):498.e491-498.e499. doi: 10.1016/j.ajog.2019.02.058. Accessed January 18, 2023.
12. Chen J, Tian D-C, Zhang C, et al. Incidence, mortality, and economic burden of myasthenia gravis in China: A nationwide population-based study. *The Lancet Regional Health - Western Pacific*. 2020;5(100063). https://doi.org/10.1016/j.lanwpc.2020.100063. Accessed January 18, 2023.

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