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For immediate release

Unique molecular properties of nipocalimab enabling differentiated potential in treating generalized myasthenia gravis to be presented at American Academy of Neurology's 2024 Annual Meeting

Analysis of clinical and non-clinical studies supports the investigational treatment's potential for rapid, deep and sustained immunoglobulin G (IgG) lowering

DENVER, Co. (April 11, 2024) – Johnson & Johnson today announced the planned presentation of new non-clinical studies underscoring the molecular properties of nipocalimab, an investigational fully human monoclonal antibody targeting the neonatal fragment crystallizable receptor (FcRn). These data showcase the promise of nipocalimab as a potential best-in-class FcRn blocker and unique characteristics including its high binding affinity and specificity to the immunoglobulin G (IgG) binding site of FcRn.[1] These properties, along with the dosing regimen chosen for study contribute to its dose- and time-dependent receptor occupancy, resulting in the rapid, deep and sustained lowering of IgG, including IgG autoantibodies in neuroimmune diseases such as generalized myasthenia gravis (gMG) and other autoantibody-driven diseases.[1] The data will be one of six scientific posters the Company will present at the American Academy of Neurology's (AAN) 2024 Annual Meeting (Poster 14-008).

[111]gMG is a highly debilitating, rare autoantibody-driven disease for which there currently is no cure, characterized by fluctuating weakness of the skeletal muscles leading to symptoms like difficulty speaking and swallowing.[1] A Phase 2 clinical study with nipocalimab published in *Neurology* (2024) demonstrated MG patients with a greater magnitude of IgG lowering tended to have greater improvements in key efficacy outcomes (e.g., MG-ADL[a]).[2]

"These new data offer additional evidence for the potential of nipocalimab to deliver optimized treatment outcomes for autoantibody-driven neurological diseases like gMG," said Sindhu Ramchandren, M.D., Clinical Development Leader, Neuroscience, Johnson & Johnson Innovative Medicine. "A significant unmet need remains for more effective treatments able to offer sustained disease control in gMG. We are encouraged by the potential of nipocalimab as a uniquely engineered treatment with characteristics which may address this gap for people living with this chronic, debilitating disease."

Nipocalimab is the only FcRn blocker being studied across three key segments of auto- and alloantibody driven diseases, including Maternal Fetal, Rare Autoantibody and Prevalent Rheumatology.[1] Within the past year nipocalimab has demonstrated clinical effect in four autoantibody-driven diseases across all three segments: hemolytic disease of the fetus and newborn in Maternal Fetal, gMG in Rare Autoantibody, and Sjögren's disease and rheumatoid arthritis in Prevalent Rheumatology. Nipocalimab exhibits non-pH-dependent, high binding affinity, enabling it to decrease maternal circulating IgG levels and block maternal to fetal IgG transfer with minimal evidence of transplacental transfer to the fetus. These properties contribute to the position of nipocalimab as the only FcRn blocker being studied in maternal fetal indications.[1] Not only are these indications of high unmet medical need, but generating data in pregnancy is differentiating because approximately 80 percent of patients living with autoantibody-driven diseases are female, and up to half are of childbearing potential.[11 3,4]

"We are pleased to present new data for nipocalimab at the AAN 2024 Annual Meeting underscoring our unwavering pursuit of best-in-class treatments for autoantibody diseases," said Katie Abouzahr, M.D., Vice President, Autoantibody and Maternal Fetal Immunology Disease Area Leader, Johnson & Johnson Innovative Medicine. "We are committed to leveraging our neuroscience and immunology expertise, understanding of immune-mediated disease, and comprehensive studies of nipocalimab to potentially deliver transformative therapies that may result in sustained symptom-free remission for patients."

Nipocalimab was granted Fast Track designation in HDFN and warm autoimmune hemolytic anemia (wAIHA) in July 2019, gMG in December 2021 and fetal neonatal alloimmune thrombocytopenia (FNAIT) in March 2024 and was granted 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 U.S. Food and Drug Administration (FDA). The investigational treatment for HDFN was also granted Breakthrough Therapy

Designation by the FDA in February 2024, and orphan medicinal product designation by the European Medicines Agency in October 2019.

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.

About generalized myasthenia gravis (gMG)

Myasthenia gravis (MG) is an autoantibody disease where autoantibodies target proteins at the neuromuscular junction, disrupt neuromuscular signaling, and impair or prevent muscle contraction.[5] The disease impacts an estimated 700,000 people worldwide, with 85% of these patients experiencing the more extensive form of the disease, gMG.[5] In MG, the immune system mistakenly attacks muscle receptors by producing anti-receptor antibodies (e.g.,anti-acetylcholine receptor [AChR], anti-muscle-specific kinase [MuSK] or anti-low density lipoprotein-related protein 4 [LRP4]) that can block or destroy these muscle receptors, preventing signals from transferring from nerves to muscles.[6] Symptoms include limb weakness, drooping eyelids, double vision, and difficulties with chewing, swallowing, speech, and breathing.[7,8] 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.

About nipocalimab

Nipocalimab is an investigational, high-affinity, fully human, aglycosylated, effectorless, monoclonal antibody that aims to selectively block FcRn to reduce levels of circulating immunoglobulin G (IgG antibodies, including autoantibodies and alloantibodies that underlie multiple conditions.[9] Nipocalimab is the only FcRn blocker being studied across three key segments in the autoantibody space: 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 alloantibodies (e.g., hemolytic disease of the fetus and newborn and fetal and neonatal alloimmune thrombocytopenia); and Prevalent Rheumatology (e.g., rheumatoid arthritis, Sjögren's disease, and systemic lupus erythematosus).[10,11,12,13,14,15,16,17,18] Blockade of FcRn has the potential to reduce overall IgG including pathogenic alloantibody levels while preserving immune function without causing broad immunosuppression. Blockade of IgG binding to FcRn in the placenta is also believed to prevent transplacental transfer of maternal alloantibodies to the fetus.[19,20]

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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[1] Nilufer Seth, et al. Nipocalimab a High Affinity, Immunoselective Clinical FcRn Blocker with Unique Properties: Observations from Non-clinical and Clinical Studies. 2024.
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