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For immediate release

Johnson & Johnson reports positive topline results for nipocalimab from a Phase 3 pivotal study in generalized myasthenia gravis (gMG) and a Phase 2 study in Sjögren's Disease (SjD)

Nipocalimab showed clinical efficacy in gMG, a chronic debilitating autoantibody disease where significant unmet patient need exists for efficacious, safe therapies that offer sustained disease control

Nipocalimab is the first investigational anti-FcRn to show efficacy in SjD, one of the most prevalent, debilitating autoantibody diseases that has no approved advanced treatments

In the past 12 months, nipocalimab has demonstrated clinical effect in four different autoantibody-driven diseases

Spring House, Pa. (February 5, 2024) – Johnson & Johnson today announced topline results from the pivotal Phase 3 VIVACITY study of nipocalimab in adults living with generalized myasthenia gravis (gMG) as well as the Phase 2 DAHLIAS study of nipocalimab in adults with Sjögren's disease (SjD). Nipocalimab has demonstrated clinical effect in four autoantibody-driven diseases within the past year, including hemolytic disease of the fetus and newborn (HDFN) and rheumatoid arthritis, in addition to gMG and SjD.

In the Phase 3 VIVACITY study in gMG, nipocalimab met the primary endpoint, achieving statistically significant reduction in MG-ADL[a] score from baseline over weeks 22 to 24 compared with placebo (PBO). gMG is a chronic, life-long, rare, and highly debilitating autoantibody-driven neuromuscular disease characterized by fluctuating muscle weakness.

The primary endpoint was also met in the Phase 2 DAHLIAS dose-ranging study in SjD with a statistically significant reduction in clinESSDAI[b] score from baseline at week 24 compared with placebo (PBO). These data represent the first positive results of an investigational anti-FcRn treatment in this chronic, debilitating autoantibody disease that is without approved advanced therapies. SjD is nine times more common in women than in men, a factor of relevance to nipocalimab and the investigative treatment's unique status among anti-FcRns, with acceptable benefit-risk demonstrated in studies in pregnant individuals thus far.

Nipocalimab was well-tolerated by participants in both studies.

"We look forward to sharing the comprehensive results of these important studies at upcoming scientific medical meetings," said Katie Abouzahr, M.D., Vice President, Autoantibody and Maternal Fetal Immunology Disease Area Leader, Johnson & Johnson. "Johnson & Johnson is committed to addressing the immense unmet patient need in these chronic and debilitating autoantibody-driven diseases. We are the only company developing an anti-FcRn treatment in three key segments of autoantibody disease and have achieved proof of concept in each: Rare Autoantibody with gMG, Maternal Fetal Immunology with HDFN, and Prevalent Rheumatology with today's results in SjD building on our existing data in rheumatoid arthritis."

As next steps, Johnson & Johnson plans to present full results from the Phase 3 VIVACITY study at an upcoming scientific medical congress and engage with global regulatory authorities about bringing

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nipocalimab to patients living with gMG. The results from the Phase 2 DAHLIAS study support further clinical development of nipocalimab in SjD, and the full results from the study will be presented at a scientific medical congress this year.

Nipocalimab was granted Fast Track designation in HDFN and warm autoimmune hemolytic anemia (wAIHA) in July 2019 and gMG in December 2021, 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 fetal and neonatal alloimmune thrombocytopenia (FNAIT) in December 2023 by the U.S. Food and Drug Administration (FDA). The treatment was also granted orphan medicinal product designation by the European Medicines Agency in October 2019 for HDFN. Nipocalimab is under development and not currently approved.

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. ClinESSDAI is an endpoint specific to SjD and is a composite scale that assesses organ disease activity across 11 organ system domains [cutaneous, pulmonary, renal, articular, muscular, peripheral nervous system (PNS), central nervous system (CNS), hematological, glandular, constitutional, lymphadenopathy and lymphoma]; a higher score indicates greater symptom severity.

About the Phase 3 VIVACITY study of nipocalimab in gMG

The Phase 3 VIVACITY study was a randomized, double-blind, placebo (PBO)-controlled study in adult patients with moderate to severe gMG with insufficient response to standard-of-care therapies.

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. The disease impacts an estimated 700,000 people worldwide, with 85% of these patients experiencing the more extensive form of the disease, gMG.[1] 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. Symptoms include limb weakness, drooping eyelids, double vision, and 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.

About the Phase 2 DAHLIAS study of nipocalimab in SjD

The Phase 2 DAHLIAS study was a randomized, double-blind, placebo (PBO)-controlled dose-ranging study in patients with SjD who had moderate to severe disease activity on standard of care.

About Sjögren's disease (SjD)

Sjögren's disease (SjD) is one of the most prevalent autoantibody driven diseases for which no therapies are currently approved that treat the underlying and systemic nature of the disease.[2] It is a chronic autoimmune disease that is estimated to impact approximately 350,000 people in the U.S. and 560,000 across the U.S. and Europe,[3] and is nine times more common in women than men,[4] characterized by autoantibody production, chronic inflammation, and lymphocytic infiltration of exocrine glandular systems. Most patients are affected by mucosal dryness (eyes, mouth, vagina), joint pain, and fatigue. Extraglandular manifestations are common and may impact multiple organ systems, including joints, lungs, kidneys, and nervous system. Patients with SjD have a high risk of developing numerous associated conditions, including up to 20 times higher risk of developing B-cell lymphomas when

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compared to the general population. Disease burden can be as high as that of rheumatoid arthritis or systemic lupus erythematosus. It is usually associated with impaired quality of life and functional capacity.[5,6]

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.[7] Nipocalimab is the only anti-FcRn being studied across three key segments in the autoantibody space: Rare Autoantibody (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., HDFN); and Prevalent Rheumatology (e.g., rheumatoid arthritis, SjD, and systemic lupus erythematosus)[8-15] Blockade of FcRn has the potential to reduce overall autoantibody 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.[16]

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.

Learn more at https://www.jnj.com/ or at www.janssen.com/johnson-johnson-innovative-medicine. Follow us at @JanssenUS and @JNJInnovMed.

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 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 the 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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