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Nipocalimab pivotal Phase 3 trial demonstrates sustained disease control in FcRn class for a broad population of myasthenia gravis patients

First FcRn blocker to demonstrate superiority in Myasthenia Gravis - Activities of Daily Living score (MG-ADL)[a] over placebo when added to standard of care over 24 weeks in antibody positive patients: anti-AChR+, anti-MuSK+ and anti-LRP4+

BEERSE, BELGIUM (28 June 2024) – Janssen-Cilag International NV, a Johnson & Johnson company today announced positive results from the nipocalimab Phase 3 Vivacity-MG3 study in patients with generalised myasthenia gravis (gMG). Patients treated with nipocalimab plus standard of care (SOC) achieved superiority over placebo plus SOC as measured by the primary endpoint of improvement in the Myasthenia Gravis - Activities of Daily Living (MG-ADL)[a] score from baseline over 24 weeks.[1] These data are included in a presentation (Abstract #EPR014) and are among eight abstracts that Johnson & Johnson will present at the European Academy of Neurology (EAN) 2024 Congress, taking place in Helsinki from 29 June–2 July,[1] and will be included in submissions to regulatory authorities later this year.

“The sustained response of nipocalimab over six months among this broad myasthenia gravis population is an important finding given the chronic, unpredictable exacerbations typically seen with myasthenia gravis,” said Carlo Antozzi, M.D., Neuroimmunology and Muscle Pathology Unit of the Neurological Institute Foundation C. Besta of Milan, Italy.[b] “We are encouraged by the potential of nipocalimab to uniquely address this gap for people living with myasthenia gravis.”

The double-blind placebo-controlled study enrolled a broad population of 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+) patients, which account for approximately 95 percent of the gMG patient population.[1, 2] Patients receiving nipocalimab plus SOC (n=77) improved by 4.70 points on the MG-ADL[a] score versus baseline, significantly more than the 3.25 point improvement versus baseline observed with placebo plus SOC (n=76) over Weeks 22, 23 and 24 (difference of least squares means [SE], -1.45, *P*=0.002).[1,c] For someone living with gMG, a 1- to 2-point change on MG-ADL[a] score may be the difference between normal eating and frequent choking on food, or shortness of breath at rest and being on a ventilator.[3]

The overall incidence of adverse events (AEs), serious adverse events (SAEs) and AEs leading to discontinuation was similar to that in the placebo plus current SOC group; specifically, 81.6 percent of patients (n=80) treated with nipocalimab experienced AEs, closely matched by 82.7 percent (n=81) in the placebo plus SOC group. SAEs were reported by 9.2 percent of patients (n=9) in the nipocalimab group, compared to 14.3 percent (n=14) in the placebo plus SOC group.[1]

In addition to achieving the primary endpoint, critical secondary endpoints were also met:

- Improvement in strength and function of different muscle groups, as measured by Quantitative Myasthenia Gravis (QMG)[d] score, was significantly greater with nipocalimab plus SOC group demonstrating a 4.86 point improvement compared with placebo plus SOC group with a 2.05 point improvement over Weeks 22-24 (*P*<0.001).[1,e]
- MG-ADL[a] response (≥2-point improvement from baseline) was significantly greater in nipocalimab plus SOC group with 68.8 percent of participants experiencing an improvement, compared with placebo plus SOC of which 52.6 percent of participants demonstrated an improvement over Weeks 22, 23 and 24 (*P*=0.021), further underscoring the potential of treatment with nipocalimab to mitigate the impact of gMG on a patient’s day-to-day life.[1]

“We are committed to leading where medicine is going in the autoantibody diseases space,” said Ludovic de Beaucoudrey, Ph.D., Senior Director, Therapeutic Area Lead, Immunology, Janssen-Cilag Limited, a company of Johnson & Johnson. “We are excited by the potential clinical benefit of nipocalimab in generalised myasthenia gravis

and with these promising results, we are one step closer to bringing this innovative treatment option to people living with this devastating condition."

"We are thrilled to present yet another dataset for nipocalimab at the EAN 2024 Annual Meeting highlighting our commitment to providing innovative treatments for autoantibody-driven diseases," said Katie Abouzahr, M.D., Vice President, Autoantibody and Maternal Fetal Immunology Disease Area Leader, Johnson & Johnson Innovative Medicine. "We are developing transformative therapies that have the potential to address significant unmet patient need."

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.[3]
b. Dr. Carlo Antozzi has provided consulting, advisory, and speaking services to Johnson & Johnson. He has not been paid for any media work.
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.[1]
d. 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]
e. Patients who received nipocalimab had an average score of -4.86 (SE 0.504) from baseline over Weeks 22, 23 and 24. Patients randomised to placebo plus current SOC had an average score of -2.05 (SE 0.499); difference of LS means -2.81; *P*<0.001.[1]

About Generalised Myasthenia Gravis (gMG)

Myasthenia gravis (MG) is an autoantibody disease in which autoantibodies target proteins at the neuromuscular junction, disrupt neuromuscular signalling, and impair or prevent muscle contraction.[4,5] In MG, the immune system mistakenly attacks proteins at the neuromuscular junction e.g., anti-acetylcholine receptor [AChR], anti-muscle-specific tyrosine kinase [MuSK] or anti-low density lipoprotein receptor-related protein 4 [LRP4] that can block or disrupt normal functioning, preventing signals from transferring from nerves to muscles.[6] The disease impacts between 56,000 and 123,000 people in Europe.[7] Initial disease manifestations are usually ocular but in 53 percent or more the disease is characterised 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.[5,8] Although gMG may be managed with current SOC therapies, research is needed to develop new treatments for those who may not respond well enough to or tolerate those therapies.[5]

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 standard of care (SOC) therapy were identified and 199 patients, 153 of whom were antibody positive, enrolled in the 24-week double-blind placebo-controlled trial.[9,10] Randomisation 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.[9] Baseline demographics were balanced across arms (77 nipocalimab, 76 placebo).[9] 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 QMG[c] score. Long-term safety and efficacy were further assessed in an ongoing open-label extension (OLE) phase.[10]

About Nipocalimab

Nipocalimab is an investigational high-affinity, fully human, aglycosylated, effectorless monoclonal antibody, purposefully designed to bind with high affinity to block the neonatal Fc receptor (FcRn) and reduce levels of circulating immunoglobulin G (IgG) antibodies, including autoantibodies and alloantibodies that underlie multiple conditions[11] across three key segments in the autoantibody space including; Rare Autoantibody diseases (e.g., generalised myasthenia gravis in adults and children, chronic inflammatory demyelinating polyneuropathy (CIDP), warm autoimmune haemolytic anaemia (wAIHA), and idiopathic inflammatory myopathies), Maternal Foetal diseases mediated by maternal alloantibodies (e.g., haemolytic disease of the foetus and newborn (HDFN) and foetal and neonatal alloimmune thrombocytopaenia (FNAIT)), and Prevalent Rheumatology (e.g., rheumatoid arthritis, Sjögren's disease, and systemic lupus erythematosus).[12,13,14,15,16,17,18,19,20,21]

The U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have granted several key designations to nipocalimab including:

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- U.S. FDA Fast Track designation in HDFN and wAIHA in July 2019, gMG in December 2021 and FNAIT in March 2024
- U.S. FDA Orphan drug status for wAIHA in December 2019, HDFN in June 2020, gMG in February 2021, CIDP in October 2021 and FNAIT in December 2023
- U.S. FDA Breakthrough Therapy designation for HDFN in February 2024
- Orphan medicinal product designation for HDFN by the EMA 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.

Learn more at www.janssen.com/emea. Follow us at www.linkedin.com/janssenEMEA. Janssen-Cilag International NV and Janssen-Cilag Limited are 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., Janssen-Cilag International NV 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., Janssen-Cilag International NV 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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