Johnson&Johnson

NEWS RELEASE

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

6/28/2024

First-and-only FcRn blocker to demonstrate superiority in activities of daily living (MG-ADL[a]) over placebo when added to standard of care over 24 weeks in antibody positive patients: anti-AChR+, anti-MuSK+, anti-LRP4+

HELSINKI, June 28, 2024 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced positive results from the nipocalimab Phase 3 Vivacity-MG3 study in patients with generalized 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 MG-ADL score from baseline over 24 weeks. These data are included in a presentation and are among eight abstracts that Johnson & Johnson will present at the European Academy of Neurology (EAN) 2024 Congress[1] and will be included in submissions to regulatory authorities later this year.

Experience the full interactive Multichannel News Release here:
https://www.multivu.com/players/English/9276951-johnson-and-johnson-nipocalimab-results-myasthenia-gravis-ean-2024

"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 help address this gap for people living with myasthenia gravis."

The double-blind placebo-controlled study enrolled a broad population of anti-AChR+, anti-MuSK+ and/or anti-LRP4+ patients, which account for approximately 95 percent of the gMG patient population.[2] Patients receiving nipocalimab plus SOC improved by 4.70 points on the MG-ADL, significantly more than the 3.25 point improvement from baseline observed with placebo plus SOC from baseline over Weeks 22, 23 and 24 (P=0.002)[c]. For someone living with gMG, a 1- to 2-point change on MG-ADL may be the difference between normal eating and frequent choking on food, or shortness of breath at rest and being on a ventilator.[3] In addition to achieving this primary endpoint, critical secondary endpoints were also met:

- Improvement in strength and function of different muscle groups, as measured by QMG[d], was significantly greater with nipocalimab plus SOC compared with placebo plus SOC over Weeks 22 and 24 (P<0.001)[e].
- MG-ADL response (≥2-point improvement from baseline) was significantly greater in nipocalimab plus SOC compared with placebo plus SOC (P=0.021) over Weeks 22, 23 and 24, further underscoring the potential of treatment with nipocalimab to mitigate the impact of gMG on a patient's day-to-day life.

Safety and tolerability were consistent with other nipocalimab studies. The overall incidence of adverse events, serious adverse events and adverse events leading to discontinuation was similar to that in the placebo plus current SOC group.

"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.

b. Dr. Antozzi is a paid consultant for Johnson & Johnson. He has not been compensated 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.

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.

e. Patients who received nipocalimab had an average score of -4.86 (SE 0.504) from baseline over Weeks 22, 23 and 24. Patients randomized to placebo plus current SOC had an average score of -2.05 (SE 0.499); difference of LS means -2.81; P<0.001.

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.[4] In MG, the immune system mistakenly attacks muscle receptors by producing anti-receptor 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 destroy these muscle receptors, preventing signals from transferring from nerves to muscles.[5] The disease impacts an estimated 700,000 people worldwide. Initial disease manifestations are usually ocular but in 53 percent or more,[6,7] 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.[8,9] 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.

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 condition 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 QMG[c] score. Long-term safety and efficacy were further assessed in an ongoing OLE phase.[10]

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.[10,11,12,13,14,15,16,17,18] Blockade of IgG binding to FcRn in the placenta is also believed to prevent transplacental transfer of maternal alloantibodies to the fetus.[19,20]

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

- 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
- 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
- Breakthrough Therapy designation for HDFN by the FDA 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 **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 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.

Media contact:

Bridget Kimmel
Mobile: (215) 688-6033
bkimmel@its.jnj.com

Investor contact:

Raychel Kruper
investor-relations@its.jnj.com

Antozzi, C et al., Efficacy and Safety of Nipocalimab in patients with Generalized Myasthenia Gravis- Top Line Results from the Double-Blind, Placebo-Controlled, Randomized Phase 3 Vivacity-MG3 study. 2024 European Academy of

Neurology Congress. June 2024.
Meriggioli MN, Sanders DB. Muscle autoantibodies in myasthenia gravis: beyond diagnosis? Expert Rev Clin Immunol 2012; 8: 427–38
Hartford CA, Sherman SA, Karantzoulis S, Guillemin I, Phinney MG, Kelly KL, Negron KE, Raja SM, Rofail D. Experience of Daily Life with Generalized Myasthenia Gravis: A Qualitative Investigation and Assessment of Instrument Content Validity. Neurol Ther. 2023 Dec;12(6):2079-2099. doi: 10.1007/s40120-023-00544-y. Epub 2023 Sep 25. PMID: 37747661; PMCID: PMC10630275.
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**.
Wiendl, H., et al., Guideline for the management of myasthenic syndromes. Therapeutic advances in neurological disorders, 16, 17562864231213240. **https://doi.org/10.1177/17562864231213240**. Last Accessed April 2024.
Bever, C.T., Jr, Aquino, A.V., Penn, A.S., Lovelace, R.E. and Rowland, L.P. (1983), Prognosis of ocular myasthenia. Ann Neurol., 14: 516-519. **https://doi.org/10.1002/ana.410140504**
Kupersmith MJ, Latkany R, Homel P. Development of generalized disease at 2 years in patients with ocular myasthenia gravis. Arch Neurol. 2003 Feb;60(2):243-8. doi: 10.1001/archneur.60.2.243. PMID: 12580710.
Myasthenia gravis fact sheet. Retrieved April 2024 from **https://www.ninds.nih.gov/sites/default/files/migrate-documents/myasthenia_gravis_e_march_2020_508c.pdf**.
Myasthenia Gravis: Treatment & Symptoms. (2021, April 7). Retrieved April 2024 from **https://my.clevelandclinic.org/health/diseases/17252-myasthenia-gravis-mg**.
ClinicalTrials.gov Identifier: NCT04951622. Available at: **https://clinicaltrials.gov/ct2/show/NCT04951622**. Last accessed: June 2024.
ClinicalTrials.gov. NCT03842189. Available at: **https://clinicaltrials.gov/ct2/show/NCT03842189**. Last accessed: June 2024
ClinicalTrials.gov Identifier: NCT05327114. Available at: **https://www.clinicaltrials.gov/study/NCT05327114**. Last accessed: June 2024
ClinicalTrials.gov Identifier: NCT04119050. Available at: **https://clinicaltrials.gov/study/NCT04119050**. Last accessed: June 2024.
ClinicalTrials.gov Identifier: NCT05379634. Available at: **https://clinicaltrials.gov/study/NCT05379634**. Last accessed: June 2024.
ClinicalTrials.gov Identifier: NCT05912517. Available at: **https://www.clinicaltrials.gov/study/NCT05912517**. Last accessed: June 2024
ClinicalTrials.gov Identifier: NCT06028438. Available at: **https://clinicaltrials.gov/study/NCT06028438**. Last accessed: June 2024.
ClinicalTrials.gov Identifier: NCT04968912. Available at: **https://clinicaltrials.gov/study/NCT04968912**. Last accessed: June 2024.

ClinicalTrials.gov Identifier: NCT04882878. Available at: **https://clinicaltrials.gov/study/NCT04882878**. Last accessed: June 2024.
Lobato G, Soncini CS. Relationship between obstetric history and Rh(D) alloimmunization severity. Arch Gynecol Obstet. 2008 Mar;277(3):245-8. DOI: 10.1007/s00404-007-0446-x. Last accessed: June 2024.
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.

View original content:**https://www.prnewswire.com/news-releases/nipocalimab-pivotal-phase-3-trial-demonstrates-longest-sustained-disease-control-in-fcrn-class-for-broadest-population-of-myasthenia-gravis-patients-302185879.html**

SOURCE Johnson & Johnson