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Johnson & Johnson receives positive CHMP opinion of nipocalimab to treat a broad population of antibody-positive patients living with generalised myasthenia gravis (gMG)

Pending the European Commission's final decision, nipocalimab could be the first FcRn blocker approved in both adult and adolescent gMG patients aged 12 and older who are anti-AChR or anti-MuSK antibody-positive

CHMP opinion is supported by results from the Phase 3 Vivacity-MG3 and Phase 2/3 Vibrance-mg studies over 24 weeks, which demonstrated a sustained reduction in immunoglobulin G (IgG) levels, one of the root causes of autoantibody diseases

BEERSE, BELGIUM (19 SEPTEMBER, 2025) – Johnson & Johnson today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended the approval of nipocalimab, a fully human FcRn-blocking monoclonal antibody, as an add-on to standard therapy for the treatment of generalised myasthenia gravis (gMG).[1] The recommendation is for nipocalimab in a broad population of people living with gMG including adults and adolescent patients 12 years of age and older who are anti-acetylcholine receptor [AChR] or anti-muscle-specific kinase [MuSK] antibody positive.[1,2]

"Results from the Phase 3 Vivacity-MG3 trial demonstrate nipocalimab has the potential to offer sustained disease control in a condition that is associated with fluctuations in symptoms," said Mark Graham, Senior Director, Therapeutic Area Head, Immunology, Johnson & Johnson Innovative Medicine EMEA. "Today's positive CHMP opinion is a vital step forward in our unwavering commitment to improve the treatment landscape for people living with generalised myasthenia gravis across Europe. We look forward to the European Commission's decision, which brings us closer to delivering an innovative treatment option to those who need it most."

gMG is a chronic, incurable autoantibody disease that affects approximately 56,000 to 123,000 people across Europe.[3,4,5] Patients often experience debilitating symptoms such as muscle weakness, difficulty chewing, swallowing, speaking, and breathing that severely disrupt their ability to carry out even the most basic daily activities, such as going for a walk.[4,6] There still exists an immense need for additional immune-selective treatment options that can offer sustained disease control and tolerability for people living gMG.[7]

The CHMP recommendation for nipocalimab is supported by data from the pivotal, ongoing Phase 3 Vivacity-MG3 study which showed that outcomes for anti-AChR and anti-MuSK antibody-positive adult participants who received nipocalimab plus standard of care (SOC) were superior compared to those who received placebo plus SOC.[1] The primary endpoint of the study measured improvement in the MG-ADL[a] score from baseline over 24 weeks and study participants included anti-AChR, anti-MuSK, and anti-LRP4 antibody-positive adults, which account for approximately 95% of the gMG patient population.[1] Patients who entered the open-label extension (OLE) phase after the double-blind phase and continued nipocalimab treatment, maintained improvements in the MG-ADL[a] score for up to 84 weeks, making Vivacity-MG3 the first registrational study to demonstrate sustained disease control over this duration.[8,9] Safety and tolerability were consistent with other nipocalimab studies.[10,11,12,b]

The recommendation also included data from the Phase 2/3 Vibrance-mg study of nipocalimab in anti-AChR antibody-positive adolescents (aged 12 – 17 years) living with gMG.[2] Study participants who were treated with nipocalimab plus SOC achieved sustained disease control as measured by the primary endpoint of IgG reduction from baseline over 24 weeks compared to placebo plus SOC, and secondary endpoints of improvement in MG-ADL[a] and QMG[c] scores.[2] Nipocalimab was well-tolerated over the six-month period, similar to tolerability seen in adult participants in the Vivacity-MG3 study.[2]

Today's CHMP opinion is the response to a Marketing Authorisation Application (MAA) submitted to the European Medicines Agency (EMA) for nipocalimab in gMG in September 2024.[13] The European Commission will review the CHMP recommendation and provide a decision in due course.

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.[6]
b. The overall incidence of adverse events (AEs), serious adverse events (SAEs) and AEs leading to discontinuation were similar to that in the placebo plus SOC group.[1] Specifically, 81.6% of patients (n=80) treated with nipocalimab plus SOC experienced AEs, closely matched by 82.7% (n=81) in the placebo plus SOC group.[1] Serious AEs were reported by 9.2% of patients (n=9) in the nipocalimab plus SOC group compared to 14.3% (n=14) in the placebo plus SOC group.[1]
c. QMG (Quantitative Myasthenia Gravis) is a 13-item assessment by a clinician that quantifies MG disease severity through muscle weakness.[6] The total QMG score ranges from 0 to 39, where higher scores indicated greater disease severity.[6]

ABOUT GENERALISED MYASTHENIA GRAVIS (gMG)

Myasthenia gravis (MG) is an autoantibody disease in which the immune system mistakenly makes antibodies (e.g., anti-acetylcholine receptor [AChR], anti-muscle-specific tyrosine kinase [MuSK]), which target proteins at the neuromuscular junction and can block or disrupt normal signalling from nerves to muscles, thus impairing or preventing muscle contraction.[14,15] The disease impacts between 56,000 and 123,000 people in Europe and an estimated 700,000 people worldwide.[5,16] The disease affects both men and women and occurs across all ages, racial and ethnic groups, but most frequently starts in young women and older men.[5] Roughly 50% of individuals diagnosed with MG are women, and about one in five of those women are of child-bearing potential.[17,18,19] Approximately 10 to 15% of new cases of MG are diagnosed in paediatric patients 12-17 years of age.[17,18,19] Among juvenile MG patients, girls are affected more often than boys with over 65% of paediatric MG cases in the EU diagnosed in girls.[20,21,22]

Initial disease manifestations are usually eye-related but approximately 85% of MG patients experience additional advancements to the disease manifestations - referred to as generalised myasthenia gravis (gMG).[23] This is characterised by severe muscle weakness and difficulties in speech and swallowing.[4,24] Vulnerable gMG populations, such as paediatric patients, have more limited therapeutic options.[25]

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.[26] Antibody positive or negative adult gMG patients with insufficient response (MG-ADL ≥6) to ongoing SOC therapy were identified and 199 patients, 153 of whom were antibody positive, enrolled in the 24-week double-blind placebo-controlled trial.[26] 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.[26,27] Baseline demographics were balanced across arms (77 nipocalimab, 76 placebo).[1] The primary efficacy endpoint was the comparison of the mean change from baseline to Weeks 22, 23, and 24 between treatment groups in the MG-ADL total score.[26] A key secondary endpoint included change in QMG score. Long-term safety and efficacy were further assessed in an ongoing open-label extension (OLE) phase.[27]

ABOUT THE PHASE 2/3 VIBRANCE-MG STUDY

The Phase 2/3 Vibrance-mg study (NCT05265273) is an on-going open-label study to determine the effect of nipocalimab in paediatric participants with gMG.[28] Seven participants aged 12 – 17 years with a diagnosis of gMG as reflected by a Myasthenia Gravis Foundation of America (MGFA) Class of II through IV at screening, and an insufficient clinical response to ongoing, stable SOC therapy, have been enrolled in the trial.[2] Participants must have a positive blood test for either anti-AChR or anti-MuSK autoantibodies.[25] The study consists of a screening period of up to four weeks, a 24-week open-label Active Treatment Phase during which participants receive nipocalimab intravenously every two weeks, and a Long-term Extension Phase; a safety follow-up assessment will be conducted at eight weeks after last dose.[2,25] The primary outcome of the study is the effect of nipocalimab on total serum IgG, safety and tolerability, and pharmacokinetics in paediatric participants with gMG at 24 weeks.[25] Secondary endpoints include change in MG-ADL and QMG scores at 24 weeks.[2]

ABOUT NIPOCALIMAB

Nipocalimab is a monoclonal antibody, designed to bind with high affinity to block FcRn and reduce levels of circulating immunoglobulin G (IgG) antibodies that underlie generalised myasthenia gravis (gMG) without additional detectable effects on other adaptive and innate immune functions.[26,29] Nipocalimab is currently approved in the U.S. for the treatment of gMG in adults and paediatric patients 12 years of age and older who are anti-AChR or anti-MuSK antibody positive.[30]

Nipocalimab is continuing to be investigated across three key segments in the autoantibody space including Rare Autoantibody diseases, Maternal Foetal diseases mediated by maternal alloantibodies and Rheumatic diseases.[25,31,32,33,34,35,36,37,38,39] The investigational monoclonal antibody is designed to bind with high affinity to block FcRn and reduce levels of circulating immunoglobulin G (IgG) auto- and alloantibodies potentially without additional detectable effects on other adaptive and innate immune functions.[29,40]

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

- EU EMA Orphan medicinal product designation for haemolytic disease of the foetus and newborn (HDFN) in October 2019 and foetal and neonatal alloimmune thrombocytopenia (FNAIT) in April 2025
- U.S. FDA Fast Track designation in HDFN and warm autoimmune haemolytic anaemia (wAIHA) in July 2019, gMG in December 2021, FNAIT in March 2024 and Sjögren's disease (SjD) in March 2025
- U.S. FDA 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
- U.S. FDA Breakthrough Therapy designation for HDFN in February 2024 and for Sjögren's disease in November 2024
- U.S. FDA granted Priority Review in gMG in Q4 2024

ABOUT JOHNSON & JOHNSON

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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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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 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 behaviour 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 most recent Annual Report on Form 10-K, 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. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

Source: Johnson & Johnson

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