

News Release

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**Janssen Showcases Phase 2 Nipocalimab (M281) Data in Adults with
Generalized Myasthenia Gravis (gMG) at the 2021 American Academy of
Neurology Virtual Meeting**

*Full results from the Vivacity-MG study to be presented for the first time during an
oral presentation*

Titusville, N.J., April 16, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the full results from the Phase 2 Vivacity-MG study of the investigational compound, nipocalimab (M281), in generalized myasthenia gravis (gMG)—a chronic, autoimmune neuromuscular disease. The data will be featured as part of an oral presentation at the American Academy of Neurology (AAN) Virtual Meeting taking place April 17-22, 2021.

Vivacity-MG presentation details are as follows:

- Program #S29.002; Session S29: Autoimmune Neurology: Clinical Trials, Treatment, and Diagnosis of CNS and PNS Autoimmune Neurologic Disorders; Wednesday, April 21, 4:08 p.m. EDT.

The Vivacity-MG study examined the safety, tolerability, and efficacy of nipocalimab in addition to standard of care treatment compared with placebo and standard of care treatment in 68 patients with moderate-to-severe gMG who had an insufficient response

to ongoing, standard of care treatment. Patients were randomized across four active dosing arms and placebo, with a primary efficacy endpoint of Myasthenia Gravis Activities of Daily Living (MG-ADL) score. MG-ADL is a validated and readily used outcome measure that assesses the symptoms that most impact a patient's daily life.

"When it comes to the treatment of myasthenia gravis, the utility of currently available medicines is limited, and many patients fail to adequately respond. This may lead to uncontrolled symptoms or significant side effects, resulting in an impact on not only their daily lives but their families and caregivers as well," said Luc Truyen, M.D., Ph.D., Global Head, Development and External Affairs, Janssen Research & Development, LLC. "The results from the Phase 2 Vivacity-MG study are promising, and we look forward to continuing to advance nipocalimab to Phase 3 clinical trials in gMG in the near future."

Additional secondary endpoints were evaluated, including the efficacy of nipocalimab as measured by changes in the Quantitative Myasthenia Gravis (QMG) score and the revised Myasthenia Gravis Quality of Life 15-item (MG-QoL15) scale from baseline, as well as the pharmacokinetics and the pharmacodynamics activity of nipocalimab as measured by effects on total serum Immunoglobulin G (IgG) concentrations. The safety and tolerability of nipocalimab were also evaluated as part of the study.

"At Janssen, we are deeply rooted in our mission to further research and development for novel medications that address unmet needs faced by those living with central nervous system disorders, including rare, neuroimmune diseases like MG," said Bill Martin, Ph.D., Global Therapeutic Area Head, Neuroscience, Janssen Research & Development, LLC. "We're extremely encouraged by these results and are pleased to showcase our expansion into neuroimmunology on a stage as prominent as the 2021 AAN Virtual Meeting."

Nipocalimab is an anti-neonatal Fc receptor (FcRn) monoclonal antibody designed to address the cause of MG by blocking FcRn and lowering IgG, including pathogenic autoantibodies. The investigational compound has been granted Orphan Drug Designation by the U.S. Food & Drug Administration for the treatment of MG.

About Generalized Myasthenia Gravis (gMG)

Myasthenia gravis (MG) is a chronic autoimmune neuromuscular disease that affects skeletal muscles responsible for eye movements, breathing, and body motion, causing muscle weakness and fatigue. The disease impacts an estimated 700,000 people

worldwide and approximately 36,000 to 60,000 patients in the U.S.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. In generalized myasthenia gravis (gMG), the blocking and destruction of muscle receptors over time leads to symptoms such as limb weakness, drooping eyelids, double vision, as well as 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 Nipocalimab

Nipocalimab (M281) is a high affinity, fully human, aglycosylated, effectorless IgG1 anti-FcRn monoclonal antibody. In patients with gMG, nipocalimab is expected to improve nerve-to-muscle signals and muscle function, thus alleviating the clinical signs and symptoms of gMG.

Nipocalimab is also being evaluated in two ongoing clinical trials: The Energy Study and Unity. The Energy Study is the Company's adaptive Phase 2/3 clinical study of nipocalimab in warm autoimmune hemolytic anemia (wAIHA) and Unity is the Company's global, multi-center, Phase 2 clinical study of nipocalimab in hemolytic disease of the fetus and newborn (HDFN) in pregnant adults at risk for severe HDFN.

Vivacity-MG Study Design

Vivacity-MG is a Phase 2, multicenter, randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, efficacy, pharmacokinetics, pharmacodynamics, and immunogenicity of nipocalimab administered to adults with gMG. 68 anti-receptor antibody-positive patients were randomized 1:1:1:1:1 to 4 treatment groups or a placebo group. To maintain study blinding, all patients received an intravenous infusion (either nipocalimab or placebo) every other week for a total of 5 infusions during the 8-week treatment period. After completion of the follow-up period, patients could enroll in a separate open-label extension study and receive treatment with nipocalimab.

The Janssen Pharmaceutical Companies of Johnson & Johnson gained full global rights to nipocalimab through the acquisition of Momenta Pharmaceuticals, Inc., a company that discovers and develops novel therapies for immune-mediated diseases, in August 2020.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal. Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding 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, any of the other Janssen Pharmaceutical Companies 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; 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 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent 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 the Janssen Pharmaceutical Companies 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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ⁱ Chen J, Tian D-C, et al. Incidence, mortality, and economic burden of myasthenia gravis in China: A nationwide population-based study. *The Lancet Regional Health - Western Pacific*, 5, 100063. 2020. Available at: <https://doi.org/10.1016/j.lanwpc.2020.100063>.