Post-Hoc Analysis of Clinically Relevant Anti-Vaccine and Anti-Virus Antibodies in Patients Treated with Nipocalimab in Vivacity-MG3 Study

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Faye Yu,[1] Eugene Myshkin,[1] Sindhu Ramchandren,[2] Ricardo Rojo Cella,[3] Robert Edwards,[3] Matthew J. Loza,[3] Dessislava Dimitrova,[3] Carolyn Cuff,[1] Sheng Gao[3*]

[1]Johnson & Johnson, Cambridge, MA, USA; [2]Johnson & Johnson, Titusville, NJ, USA; [3]Johnson & Johnson, Spring House, PA, USA

Presenting author

Introduction

- In humans, the neonatal fragment-crystallizable receptor (FcRn) maintains immunoglobulin G (IgG) levels by selectively binding to endogenous IgG and preventing its lysosomal degradation.[1]
- In autoimmune disorders like myasthenia gravis (MG), the accumulation of pathogenic IgG takes place. FcRn inhibitors are designed to selectively block the interaction of FcRn with IgG reducing the circulating levels of pathogenic IgG.[1]
- Nipocalimab is a fully-human, aglycosylated, effectorless monoclonal antibody that binds to FcRn with high specificity and high affinity. It prevents FcRn-mediated recycling of IgG without largely affecting the adaptive and innate immunity.[2]
- In the Phase 3 Vivacity-MG3 study (NCT04951622), nipocalimab treatment demonstrated rapid, substantial, and sustained lowering of total IgG and sustained disease control in patients with generalized MG (gMG).[3]
- Additionally, in the vaccine challenge study (NCT05827874), nipocalimab was shown not to impact development of IgG responses to T-cell-dependent/-independent vaccines.[4]
- Nipocalimab is US-FDA approved for gMG and may have clinical application in IgG-driven, autoantibody- and alloantibody-mediated diseases.[2]

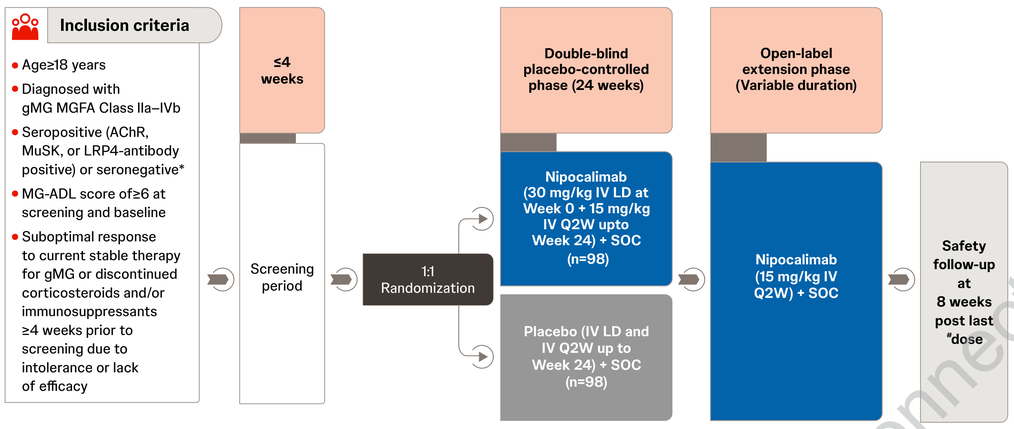
Objective

- **To evaluate the impact of nipocalimab on pre-existing clinically relevant anti-vaccine antibodies and humoral response to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) challenge in Vivacity-MG3 patients in the double-blind (DB) phase.**

Methods

- Patients received nipocalimab (n=98; 30 mg/kg loading dose followed by 15 mg/kg every 2 weeks afterwards) or placebo (n=98; loading dose and intravenously every 2 weeks) for 24 weeks in the DB period, **Figure 1**.
- The post-hoc analysis included only samples in the DB phase.

Figure 1: Study design



*In all countries seronegative except France. #Patients who withdrew or discontinue after receiving any amount of study intervention will be required to complete a safety follow-up visit 8 weeks after the last infusion. **AChR**=acetyl choline receptor, **gMG**=generalized myasthenia gravis, **IV**=intravenous, **LD**=loading dose, **LRP4**=low-density lipoprotein-related protein, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **MGFA**=Myasthenia Gravis Foundation of America, **MuSK**=muscle specific kinase, **Q2W**=every 2 weeks, **SOC**=standard of care.

- Serum IgG antibody levels against tetanus toxoid (TT) and varicella zoster virus (VZV) were measured at baseline and in post-treatment samples in a subset of patients from Vivacity-MG3.
- In patients with available samples and documented SARS-CoV-2 vaccination or infection during the study, antibodies against different epitopes of SARS-CoV-2 were measured. Epitopes included anti-spike, anti-spike protein S1 subunit receptor binding domain and anti-nucleocapsid.

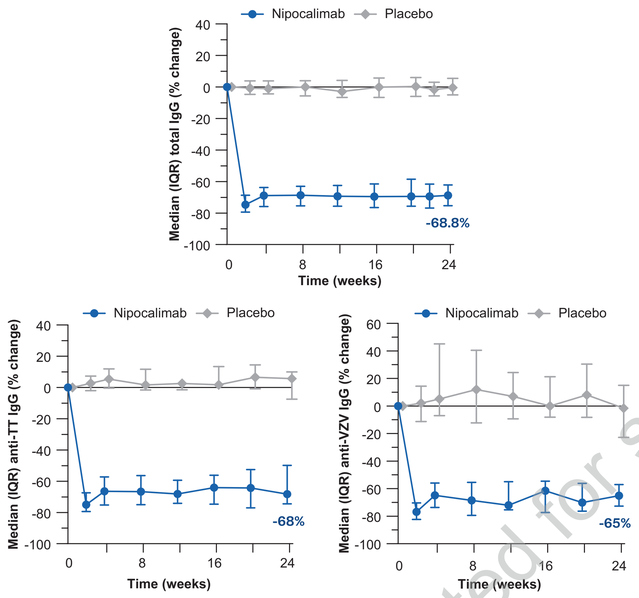
Key Takeaways

- **Nipocalimab reduced pre-existing anti-vaccine antibodies to a similar extent as total IgG, consistent with the mechanism of action of nipocalimab.**
- **Nipocalimab-treated patients largely remained protected for TT and VZV.**
- **Patients demonstrated preserved humoral responses to TT vaccination and SARS-CoV-2 infection/ vaccination; thus, supporting the compatibility of nipocalimab with recommended vaccination schedules.**

Results

- Nipocalimab reduced pre-existing anti-TT and anti-VZV antibodies similar to total IgG (observed median [intra-quartile range] pre-dose/minimal reduction at week 24: 68.8% [-62.2, -75.3]), **Figure 2**.

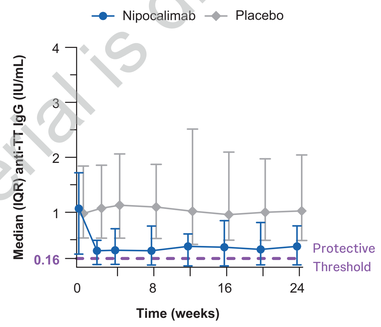
Figure 2: Observed % reduction in total IgG, anti-TT, and anti-VZV antibodies



IgG=immunoglobulin G, **IQR**=interquartile range, **TT**=tetanus toxoid, **VZV**=varicella zoster virus.

- The majority of nipocalimab-treated patients who were immune to TT (n=18) at baseline, maintained IgG antibody levels above protective thresholds during the DB treatment period, **Figure 3A**.

Figure 3A: Anti-TT IgG levels over time in nipocalimab treated patients

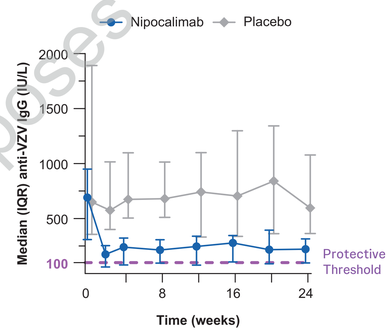


Antibody	Treatment Group	Total number of patients	N, Above PT at BL/Week 0	n/N (%), Above PT at Week 24	n/N (%), Above PT at all time points
Anti-TT IgG	Nipocalimab	21	18	10/15 (67%)	11/16 (69%)
	Placebo	16	14	12/12 (100%)	12/12 (100%)

BL=baseline, **IgG**=immunoglobulin G, **IU**=international units, **IQR**=interquartile range, **TT**=tetanus toxoid, **PT**=protective threshold (≥0.16 IU/mL). **TT**=tetanus toxoid.

- The majority of nipocalimab-treated patients who were immune to VZV (n=19) at baseline, maintained IgG antibody levels above protective thresholds during the DB treatment phase, **Figure 3B.**

Figure 3B: Anti-VZV IgG levels over time in nipocalimab treated patients

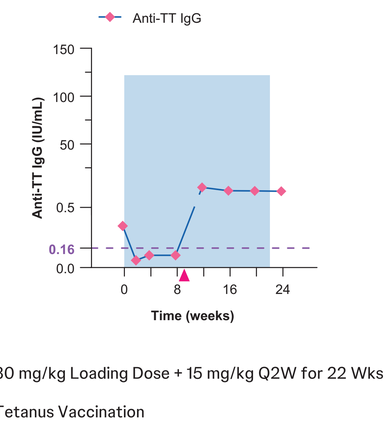


	Treatment Group	Total number of patients	N, Above PT at BL/Week 0	n/N (%), Above PT at Week 24	n/N (%), Above PT at all time points
Anti-VZV IgG	Nipocalimab	20	19	11/18 (61%)	12/19 (63%)
	Placebo	18	16	14/14 (100%)	15/16 (94%)

BL=baseline, **IgG**=immunoglobulin G, **IU**=international units, **IQR**=interquartile range, **PT**=protective threshold (≥ 100 IU/mL), **VZV**=varicella zosters virus.

- One nipocalimab-treated patient received TT vaccination during treatment and exhibited increased and sustained anti-TT levels above protective threshold post-vaccination, **Figure 4**.

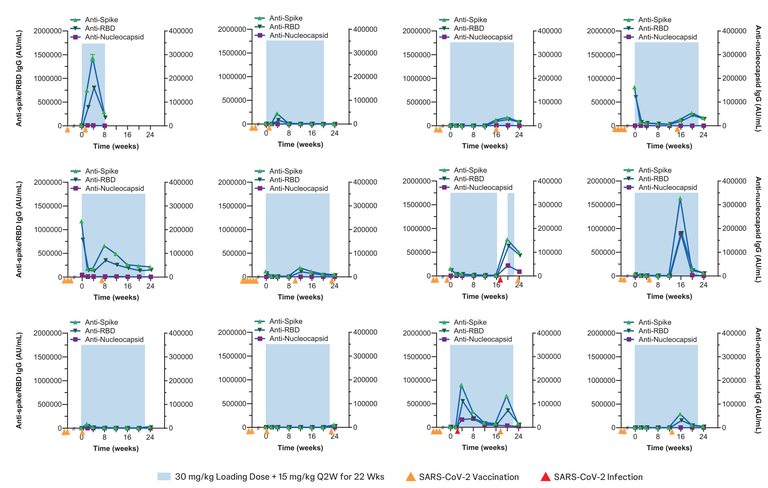
Figure 4: Anti-TT levels with TT vaccination administered during nipocalimab treatment



IgG=immunoglobulin G, **IU**=international units, **Q2W**=every 2 weeks, **TT**=tetanus toxoid, **Wks**=weeks.

- In nipocalimab-treated patients, **SARS-CoV-2 vaccination** (n=12) during treatment increased anti-spike antibodies, **Figure 5A.**

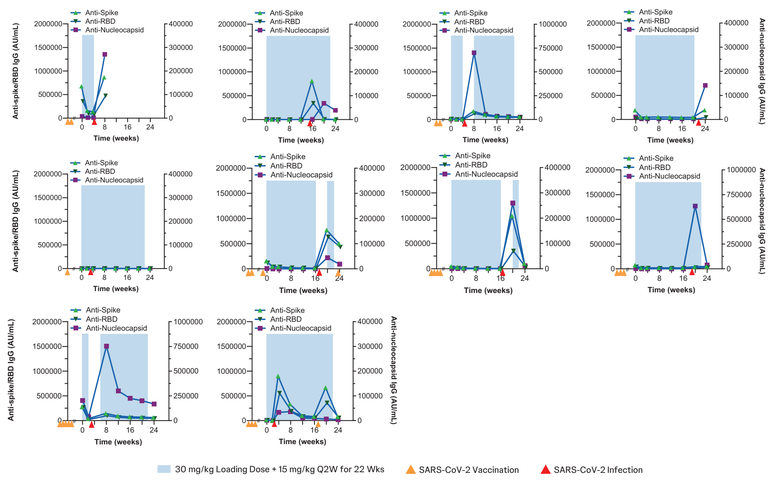
Figure 5A: Nipocalimab-treated patients after SARS-CoV-2 vaccination (n=12 patients)



IgG=immunoglobulin G, **Q2W**=every two weeks, **RBD**=receptor binding domain, **SARS-CoV-2**=severe acute respiratory syndrome coronavirus 2, **Wks**=weeks.

- In nipocalimab-treated patients, **SARS-CoV-2 infection** (n=10) led to increased anti-spike and anti-nucleocapsid antibodies, **Figure 5B.**

Figure 5B: Nipocalimab-treated patients with SARS-CoV-2 infection (n=10 patients)



IgG=immunoglobulin G, **Q2W**=every two weeks, **RBD**=receptor binding domain, **SARS-CoV-2**=severe acute respiratory syndrome coronavirus 2, **Wks**=weeks.

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