Hospital Resource Utilization Associated with Nipocalimab versus Placebo: Post-hoc Analysis of the Vivacity-MG3 Trial in Generalized Myasthenia Gravis

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Introduction

- Generalized myasthenia gravis (gMG) is a rare, chronic, IgG autoantibody-mediated disease characterized by widespread muscle weakness.[1]
- Patients can develop crises/excacerbations due to uncontrolled disease that may lead to emergency department visits (EDV) and hospital admissions (HAs) with mean length of stay of 15 days.[2]
- Nipocalimab as an add-on therapy to standard-of-care (SoC) has demonstrated statistically signifi ant sustained and meaningful improvement versus placebo+SoC in a 24-week phase 3, randomized double-blind study in adults with gMG (Vivacity-MG3).[1]

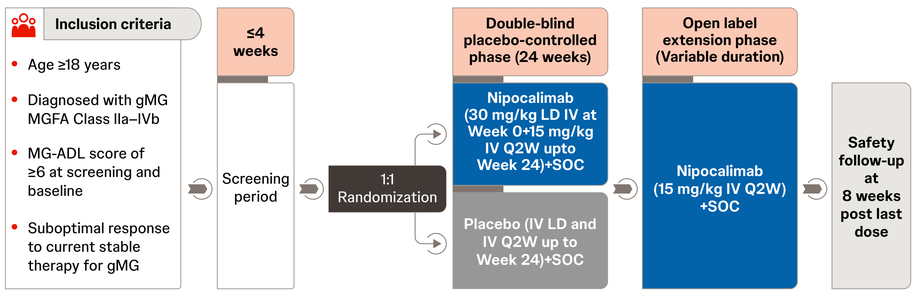
Objective

- **To evaluate all-cause and myasthenia gravis (MG)-related hospital resource utilization (HRU) and associated predictors among patients with gMG treated with Nipocalimab+SoC versus placebo+SoC**

Methods

- Primary efficacy dataset[1] was used for these analyses in both double blind (DB) and open-label extension (OLE) phase
- Details on HA, including length of stay (LoS), and EDV were collected every 12 weeks with the Hospital Resource Utilization Questionnaire (HRUQ)
- The incidence rates (IR) of HA, EDV events, and of total number of days spent in hospital, were reported per 100 patient-years (pt-yrs) by treatment group in DB phase and for those patients who continued treatment with nipocalimab+SoC in OLE phase
- Stepwise multiple logistic regression models were used to identify potential clinical and demographic characteristics associated with incidence of HA/EDV. Odds Ratios (OR) and corresponding 95% Confid nce Intervals (CI) were provided

Figure 1: Vivacity-MG3 study design



gMG=Generalized myasthenia gravis, **IV**=Intravenous, **LD**=Loading dose, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **MGFA**=Myasthenia Gravis Foundation of America, **Q2W**=Every two weeks, **SoC**=Standard-of-care.

Key Takeaways

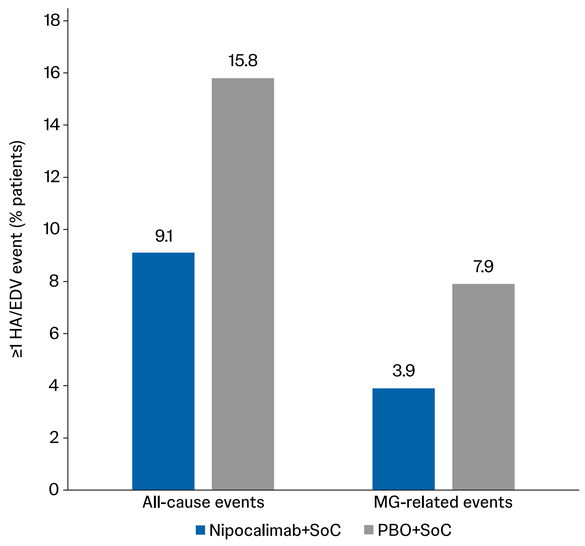
- **These analyses demonstrate that sustained disease control with nipocalimab+SoC leads to lower rates of all-cause and gMG-related HRU.**
- **HRU also substantially decreased among patients who switched from placebo+SOC to nipocalimab+SOC in OLE.**
- **Independent of treatment, potential important characteristics associated with the incidence of HA/EDV events include baseline QMG respiratory score and total MG-ADL score changes before HA/EDV event.**
- **These data highlight areas of opportunity for sustained disease control and to mitigate the HRU associated with uncontrolled disease.**

Results

Incidence rate (IR) rate of combined HA/EDV events in the DB period of Vivacity-MG3

- During the 24-weeks DB period, 9.1% and 15.8% of patients on nipocalimab+SoC (n=77) and placebo+SoC (n=76), respectively, experienced ≥1 all-cause HA/EDV event.
- Similar trends were observed for MG-related events (**Figure 2**).

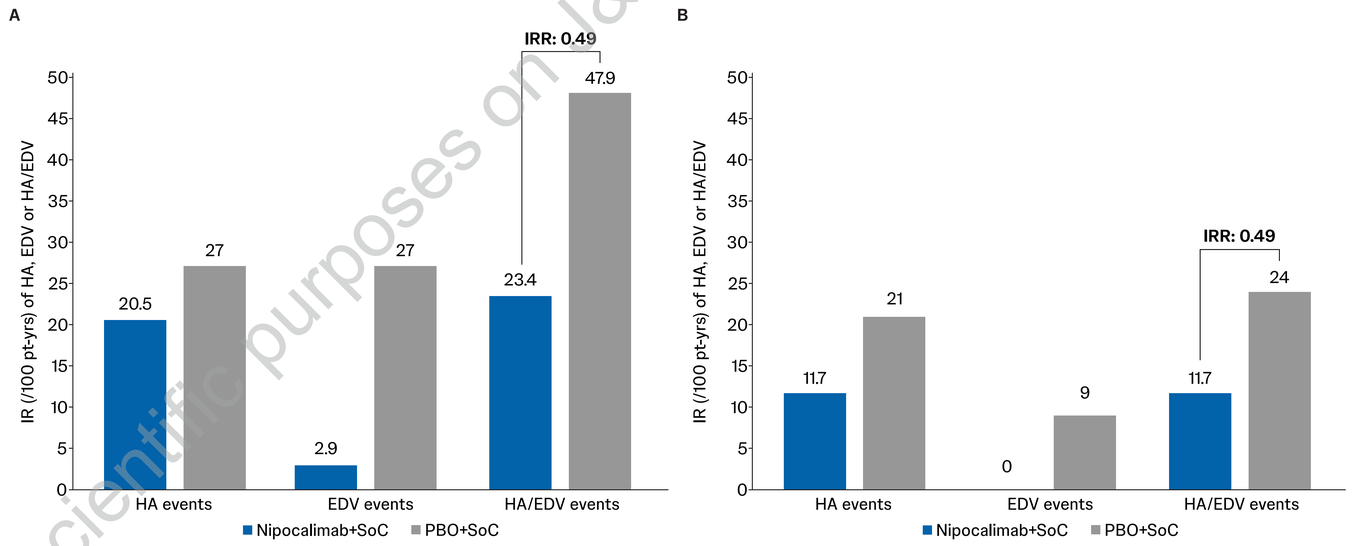
Figure 2: Proportion of patients with ≥1 all-cause and MG-related HA/EDV in the DB period of Vivacity-MG3



EDV=Emergency department visit, **HA**=Hospital admission, **MG**=Myasthenia gravis, **PBO**=Placebo, **SoC**=Standard-of-care.

- The IR of combined HA/EDV events for all-cause (**Figure 3A**) and gMG-related (**Figure 3B**) HA/EDV was numerically lower by 51% with nipocalimab+SoC than with placebo+SoC (All-cause Incidence rate ratio [IRR]: 0.49; 95% CI: 0.209-1.143; MG-related IRR: 0.49; 95% CI: 0.147-1.624).
- The lower IR of all-cause HA/EDV with nipocalimab+SoC in the DB period, 23.4 events per 100 pt-yrs, was sustained in the OLE phase at 27.3 events per 100 pt-yrs over a median follow-up of 54.1 weeks.

Figure 3: Incidence rate (IR) of all-cause (A) or MG-related (B) HA, EDV or combined HA/EDV events in the DB period of Vivacity-MG3



EDV=Emergency department visit, **HA**=Hospital admission, **IR**=Incidence rate, **MG**=Myasthenia gravis, **PBO**=Placebo, **pt-yrs**=Patient years, **SoC**=Standard-of-care.

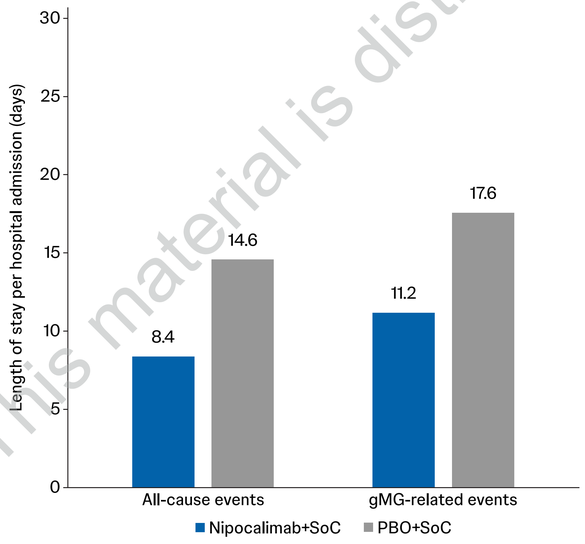
Predictors of HRU

- Multivariate analyses indicated for instance, and independent of treatment, a 1-point worsening in the MG-ADL score was associated with a 29% increase in the odds of experiencing HA/EDV (OR 1.29 [95% CI, 1.08-1.54], p=0.005).
- Additionally, a higher QMG respiratory score at baseline was associated with increased odds of HA/EDV (OR 1.73 [95% CI, 1.02-2.92], p=0.04).

Length of stay (LoS) and incidence of hospital days in the DB period of Vivacity-MG3

- The mean HA-LoS was numerically shorter by 6 days with nipocalimab+SoC than with placebo+SoC for both all-cause hospitalizations (8.4 versus 14.6 days, respectively) and for gMG-related hospitalizations (11.2 versus 17.6 days, respectively).

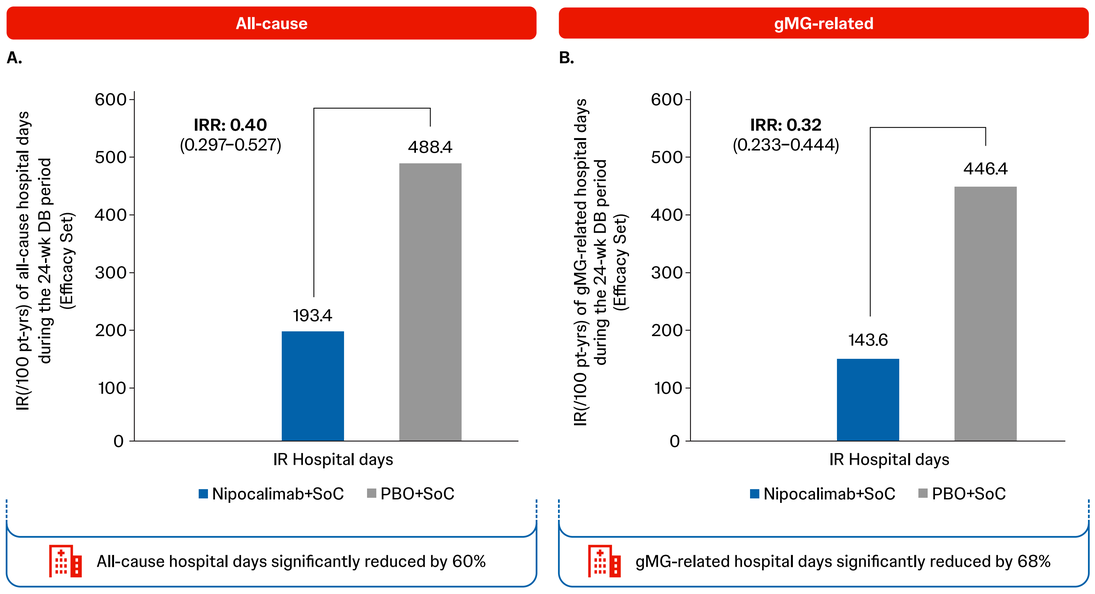
Figure 4: Length of stay (LoS) per all-cause or gMG-related hospital admission in the DB period of Vivacity-MG3.



HA=Hospital admission, **MG**=Myasthenia gravis, **PBO**=Placebo, **SoC**=Standard-of-care.

- The incidence rate of days spent in hospital (days/100 pt-yrs) for both all-cause (**Figure 5A**) and gMG-related (**Figure 5B**) HA events was signifi antly lower by 60% and 68% with nipocalimab+SoC than with placebo+SoC , respectively (All-cause IRR: 0.40; 95% CI: 0.297-0.527; gMG-related IRR: 0.32; 95%CI: 0.233-0.444).

Figure 5: Incidence rate of days spent in hospital in DB period of Vivacity-MG3, for both all cause (A) and gMG-related (B) HA events.

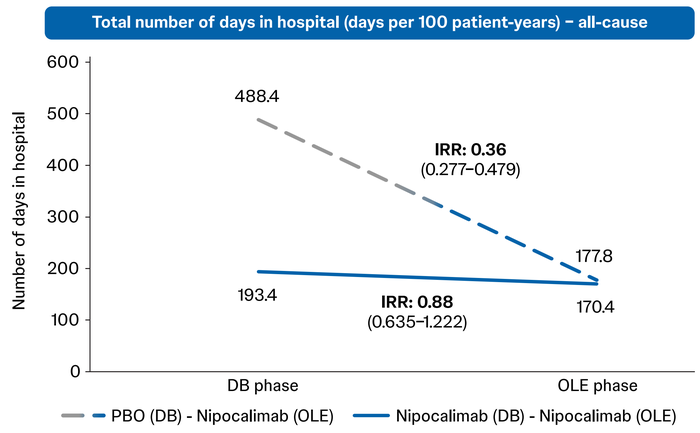


DB=Double blind, **ED**=Emergency department, **gMG**=Generalized myasthenia gravis, **IR**=Incidence rate, **IRR**=Incidence rate ratio, **PBO**=Placebo, **SoC**=Standard-of-care, **wk**=Week.

HRU in the DB to OLE Switch in Vivacity-MG3

- Incidence of days spent in hospital due to all causes signifi antly decreased when patients switched from PBO in the DB phase to nipocalimab in the OLE (IRR: 0.36; 0.277-0.479) (**Figure 6**). Similar results were seen for days spent in hospital due to gMG (data not shown).
- Patients switching from PBO to nipocalimab in the OLE had signifi antly reduced hospital resource use, aligning with levels seen in those initially randomized to nipocalimab (approx. 170 days in hospital per 100 patient-years) (**Figure 6**).

Figure 6: Total number of days in hospital for all causes after DB to OLE switch



DB=Double blind, **ED**=Emergency department, **IRR**=Incidence rate ratio, **OLE**=Open label extension, **pt-yrs**=Patient years, **PBO**=Placebo.

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