Poster #131

# Pharmacodynamic Noninferiority Study Comparing Subcutaneous Efgartigimod PH20 With Intravenous Efgartigimod: Results of Phase 3 ADAPTsc Study

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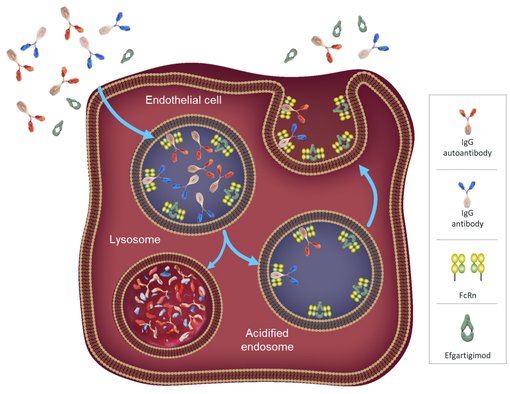
## INTRODUCTION

- Efgartigimod demonstrated clinical improvement in patients with gMG by blocking FcRn and decreasing IgG, including pathogenic IgG autoantibody levels[1,2]

### Efgartigimod Mechanism of Action: Blocking FcRn

- FcRn recycles IgG, extending its half-life and maintaining serum concentration[3]
- Efgartigimod is a human IgG1 Fc fragment, a natural ligand of FcRn, engineered for increased affinity to FcRn[4]
- Efgartigimod was designed to outcompete endogenous IgG, preventing recycling and promoting IgG lysosomal degradation without directly impacting its production[2,4–7]
  - Targeted reduction of all IgG subtypes
  - No impact on IgM or IgA
  - No reduction in albumin levels
  - No increase in cholesterol
  - No impact on IgG production



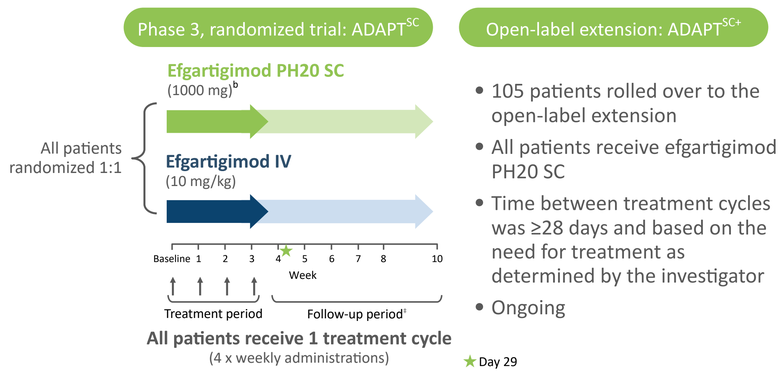

## OBJECTIVES AND METHODS

### ADAPTsc Study Design

- ADAPTsc (NCT04735432) was a phase 3, randomized, open-label, parallel-group, multicenter, noninferiority study that compared the pharmacodynamics, pharmacokinetics, efficacy, safety, tolerability, and immunogenicity of efgartigimod PH20 subcutaneous (SC; coformulated with recombinant human hyaluronidase PH20) with efgartigimod intravenous (IV) in patients with gMG[8]
- Primary endpoint: total IgG (%) reduction between efgartigimod PH20 SC and efgartigimod IV at day 29 based on a noninferiority margin of 10% in participants with gMG

adapt sc myasthenia gravis study

- Inclusion criteria:
  - Myasthenia Gravis Foundation of America class II–IV
  - MG-ADL score ≥5
  - On ≥1 stable gMG treatment[a]
  - Skin fit for injection




- 105 patients rolled over to the open-label extension
- All patients receive efgartigimod PH20 SC
- Time between treatment cycles was ≥28 days and based on the need for treatment as determined by the investigator
- Ongoing

[a]Acetylcholinesterase inhibitors, steroids, and/or NSIST. [b]Coformulated with 2000 U/mL rHuPH20. ‡Patients could not receive treatment in the 7 week follow-up period.

## RESULTS

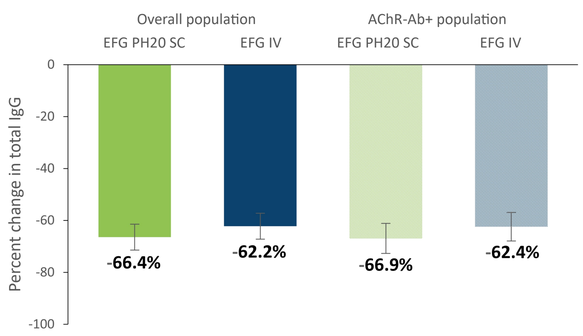
### Baseline Patient Characteristics

| | Efgartigimod PH20 SC (n=55) | Efgartigimod IV (n=55) |
|---|---|---|
| **Age**, mean (SD) years | 50.9 (15.8) | 55.8 (15.4) |
| **Female**, n (%) | 31 (56.4) | 34 (61.8) |
| **Weight**, median (min, max) kg | 78.3 (42.0, 150.2) | 78.0 (45.0, 139.3) |
| **Time since diagnosis**, mean (SD) years | 6.3 (6.4) | 7.7 (8.5) |
| **MGFA class at screening**, n (%) | | |
| Class II | 29 (52.7) | 22 (40.0) |
| Class III | 24 (43.6) | 30 (54.5) |
| Class IV | 2 (3.6) | 3 (5.5) |
| **Previous thymectomy**, n (%) | 16 (29.1) | 13 (23.6) |
| **AChR-Ab+**, n (%) | 45 (81.8) | 46 (83.6) |
| **Total MG-ADL score**, mean (SD) | 8.8 (2.6) | 8.5 (2.6) |
| **Total QMG score**, mean (SD) | 14.9 (4.4) | 15.5 (4.5) |
| **Myasthenia gravis therapies at baseline**, n (%) | | |
| Any steroid | 40 (72.7) | 33 (60.0) |
| Any NSIST[a] | 23 (41.8) | 25 (45.5) |
| Any AChEI | 48 (87.3) | 47 (85.5) |
| Steroid and NSIST[a] | 19 (34.5) | 16 (29.1) |
| AChEI only | 11 (20.0) | 12 (21.8) |

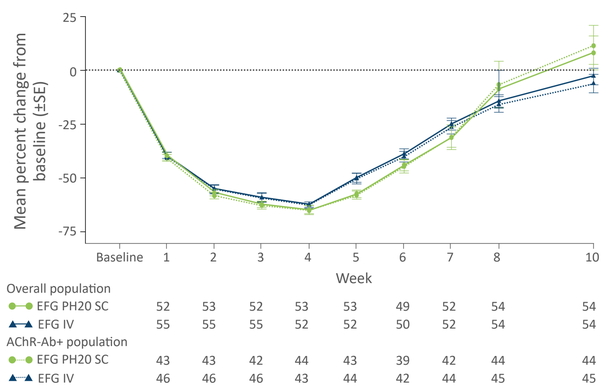
[a]Patients may have also been receiving an AChEI. NSIST: azathioprine, cyclosporine, cyclophosphamide, methotrexate, mycophenolate, tacrolimus (in mono- or combination therapy).

### Primary Endpoint of Noninferiority Between Efgartigimod PH20 SC and Efgartigimod IV in Total IgG (%) Reduction at Day 29 Was Met

**Change (%) from Baseline in Total IgG Levels at Day 29 (primary endpoint; overall and AChR-Ab+ populations)**




**Change (%) from Baseline Over Time in Total IgG Level (overall and AChR-Ab+ populations)**




| | Base- | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| Overall population | | | | | | | | | | |
| EFG PH20 SC | 52 | 53 | 52 | 53 | 53 | 49 | 52 | 54 | | 54 |
| EFG IV | 55 | 55 | 55 | 52 | 52 | 50 | 52 | 54 | | 54 |
| AChR-Ab+ population | | | | | | | | | | |
| EFG PH20 SC | 43 | 43 | 42 | 44 | 43 | 39 | 42 | 44 | | 44 |
| EFG IV | 46 | 46 | 46 | 43 | 44 | 42 | 44 | 45 | | 45 |

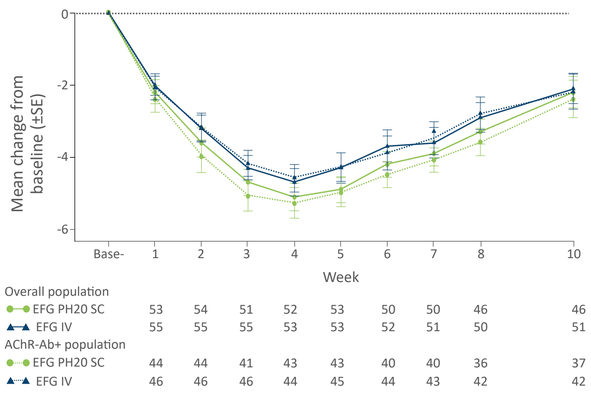
## SUMMARY

**The primary endpoint was met for noninferiority of efgartigimod PH20 SC 1000 mg to IV 10 mg/kg in terms of percent reduction from baseline in total IgG levels at Day 29, ie, 7 days after the fourth SC or IV administration**

**Safety and tolerability of efgartigimod PH20 SC was similar to efgartigimod IV, with the exception of injection-site reactions, which were all mild-to-moderate in severity and did not lead to treatment discontinuation**

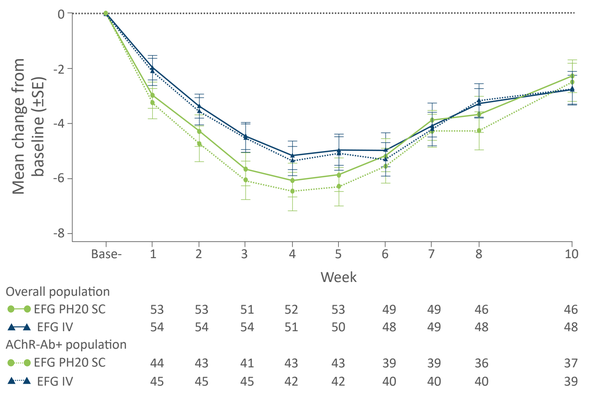
### Similar Effects Across the Multiple Efficacy Endpoints Were Reported for Both Efgartigimod PH20 SC and Efgartigimod IV

**MG-ADL Total Score Change from Baseline Over Time (overall and AChR-Ab+ populations)**



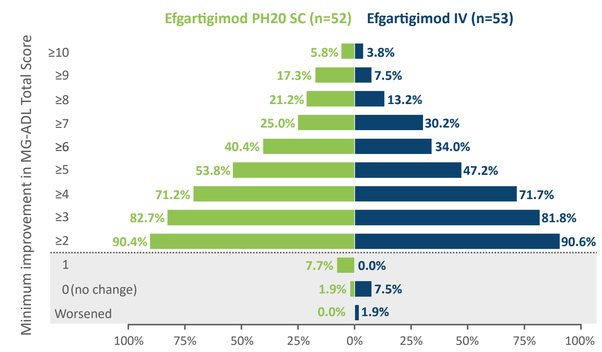

| | Base- | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| Overall population | | | | | | | | | | |
| EFG PH20 SC | 53 | 54 | 51 | 52 | 53 | 50 | 50 | 46 | | 46 |
| EFG IV | 55 | 55 | 55 | 53 | 53 | 52 | 51 | 50 | | 51 |
| AChR-Ab+ population | | | | | | | | | | |
| EFG PH20 SC | 44 | 44 | 41 | 43 | 43 | 40 | 40 | 36 | | 37 |
| EFG IV | 46 | 46 | 46 | 44 | 45 | 44 | 43 | 42 | | 42 |

**QMG Total Score Change from Baseline Over Time (overall and AChR-Ab+ populations)**

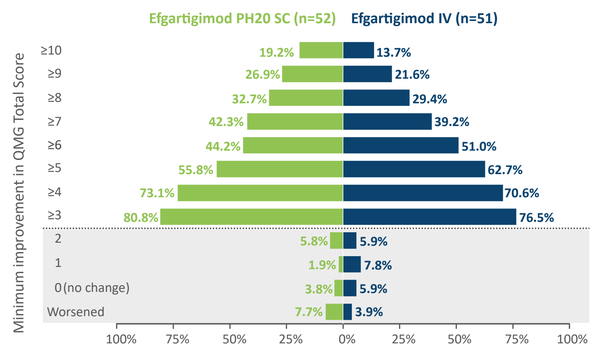



| | Base- | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| Overall population | | | | | | | | | | |
| EFG PH20 SC | 53 | 53 | 51 | 52 | 53 | 49 | 49 | 46 | | 46 |
| EFG IV | 54 | 54 | 54 | 51 | 50 | 48 | 49 | 48 | | 48 |
| AChR-Ab+ population | | | | | | | | | | |
| EFG PH20 SC | 44 | 43 | 41 | 43 | 43 | 39 | 39 | 36 | | 37 |
| EFG IV | 45 | 45 | 45 | 42 | 42 | 40 | 40 | 40 | | 39 |

**Change in MG-ADL Total Score at Week 4 (overall population)**

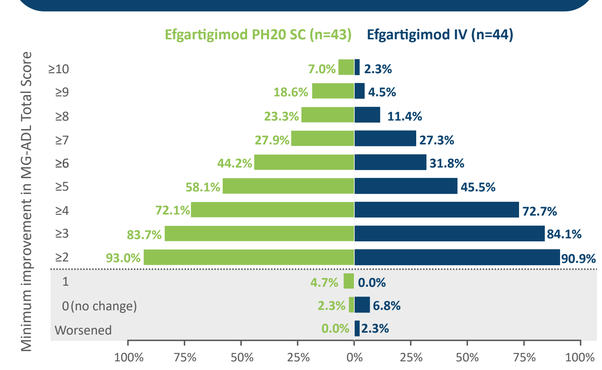



**Change in QMG Total Score at Week 4 (overall population)**

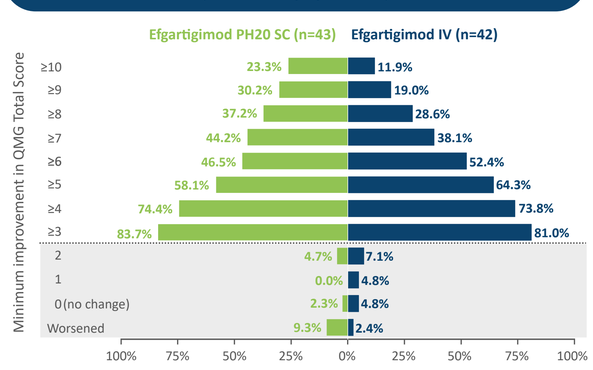



Scores above dashed line indicate clinically meaningful improvement. Minimum improvements 1 week after the last infusion of cycle 1 (week 4).

**Change in MG-ADL Total Score at Week 4 (AChR-Ab+ population)**




**Change in QMG Total Score at Week 4 (AChR-Ab+ population)**




Scores above dashed line indicate clinically meaningful improvement. Minimum improvements 1 week after the last infusion of cycle 1 (week 4).

### Summary of Adverse Events

| | Efgartigimod PH20 SC (n=55) | Efgartigimod IV (n=55) |
|---|---|---|
| **Any AE**, n (%) | 37 (67.3) | 28 (50.9) |
| **Any AE Grade ≥3**, n (%) | 9 (16.4) | 4 (7.3) |
| **Any SAE**, n (%) | 8 (14.5) | 4 (7.3) |
| **≥1 injection-site reaction (localized)**, n (%) | 21 (38.2) | 1 (1.8)[a] |
| **Any infection**, n (%) | 10 (18.2) | 9 (16.4) |
| **Discontinued study treatment due to AEs**, n (%) | 2 (3.6)[b] | 0 (0.0) |
| **Most frequent AEs occurring in ≥5 patients**, n (%) | | |
| Injection site rash | 8 (14.5) | 0 (0) |
| Headache | 7 (12.7) | 7 (12.7) |
| Injection site erythema | 7 (12.7) | 0 (0) |
| Myasthenia gravis worsening | 6 (10.9) | 1 (1.8) |
| Injection site pruritus | 5 (9.1) | 0 (0) |
| Fatigue | 2 (3.6) | 3 (5.5) |

No Grade 5 or 4 AEs reported. [a]No preferred term AEs of injection-site reaction recorded. This AE was incorrectly coded (should have been catheter site reaction). [b]1 treatment discontinuation due to COVID-19 infection on Day 3 and the other due to MG worsening on Day 1.

- Efgartigimod was generally well tolerated
- Injection-site reactions were mild (18/21 patients) or moderate (3/21 patients) and most (19/21 patients) were transient and resolved without treatment
- Worsening of gMG symptoms typically happened at the end of the follow-up period. All patients who rolled over to the open-label extension had clinically meaningful improvement in MG-ADL when they received efgartigimod again

**ABBREVIATIONS:** AChEI, acetylcholinesterase inhibitor; AChR-Ab, acetylcholine receptor antibody; AE, adverse event; EFG, efgartigimod; FcRn, neonatal Fc receptor; gMG, generalized myasthenia gravis; IgG, immunoglobulin G; IV, intravenous; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; NSIST, nonsteroidal immunosuppressive therapy; PH20, recombinant human hyaluronidase PH20; QMG, Quantitative Myasthenia Gravis; SAE, serious adverse event; SC, subcutaneous; SE, standard error.

**REFERENCES: 1.** Howard JF Jr, et al. *Neurology.* 2019;92:e2661–73. **2.** Howard JF Jr, et al. *Lancet Neurol.* 2021;20:526–36. **3.** Sesarman A, et al. *Cell Mol Life Sci.* 2010;67:2533–50. **4.** Ulrichts P, et al. *J Clin Invest.* 2018;128:4372–86. **5.** Vaccaro C, et al. *Nat Biotech.* 2005;23:1283–88. **6.** Nixon AE, et al. *Front Immunol.* 2015;6:176. **7.** Ward ES, et al. *Front Immunol*. 2022;13:892534. **8.** ADAPTsc (NCT04735432), available at: https://clinicaltrials.gov/ct2/show/NCT04735432. Accessed July 29, 2022.

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# INTRODUCTION

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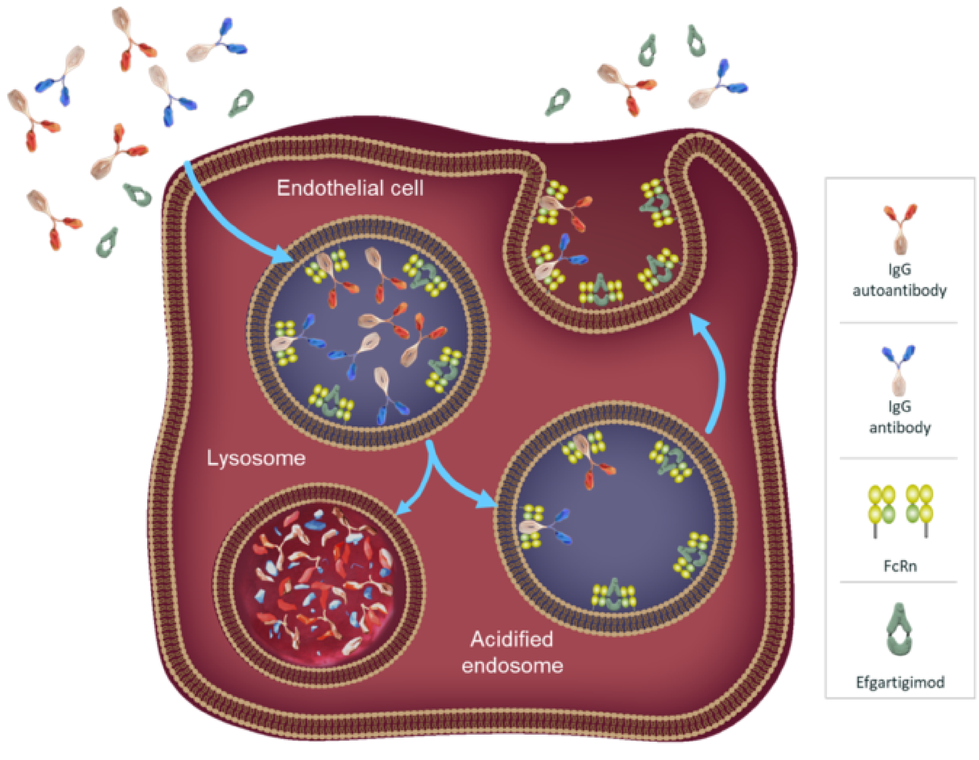

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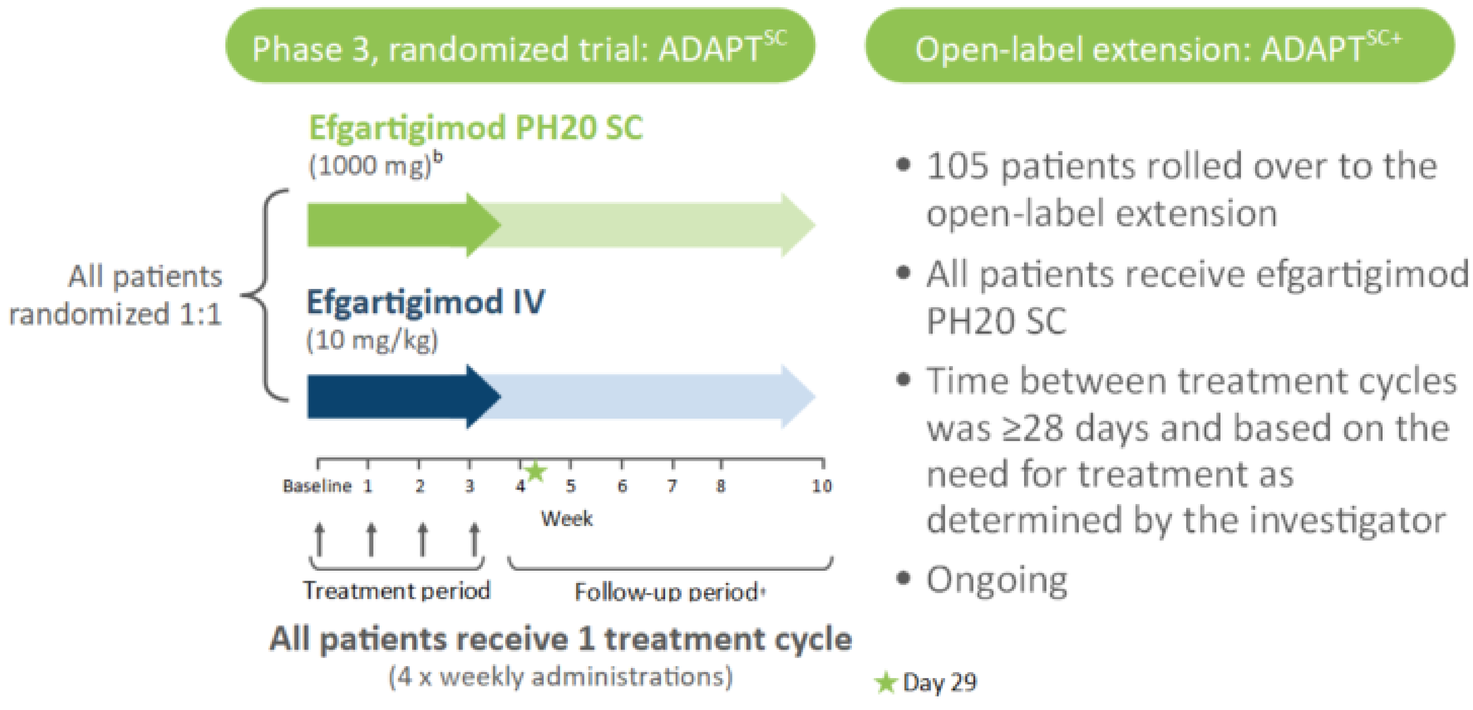


[a]Acetylcholinesterase inhibitors, steroids, and/or NSIST. [b]Coformulated with 2000 U/mL rHuPH20. ‡Patients could not receive treatment in the 7 week follow-up period.

# RESULTS

## Baseline Patient Characteristics

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| **Total QMG score**, mean (SD) | 14.9 (4.4) | 15.5 (4.5) |
| **Myasthenia gravis therapies at baseline**, n (%) | | |
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| Any NSIST[a] | 23 (41.8) | 25 (45.5) |
| Any AChEI | 48 (87.3) | 47 (85.5) |
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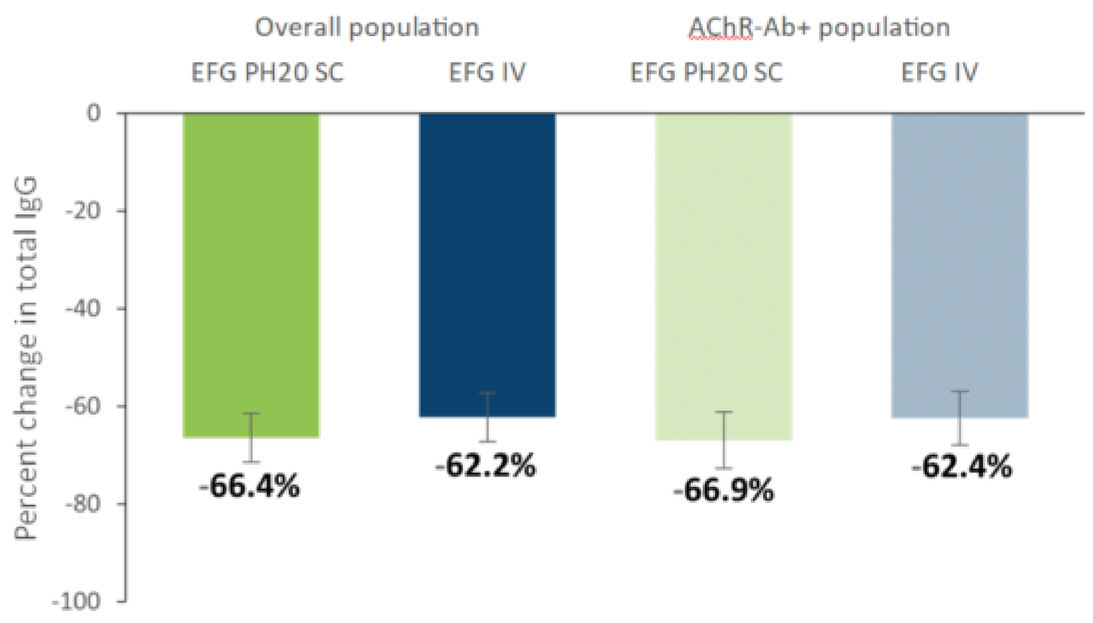
[a]Patients may have also been receiving an AChEI. NSIST: azathioprine, cyclosporine, cyclophosphamide, methotrexate, mycophenolate, tacrolimus (in mono- or combination therapy).

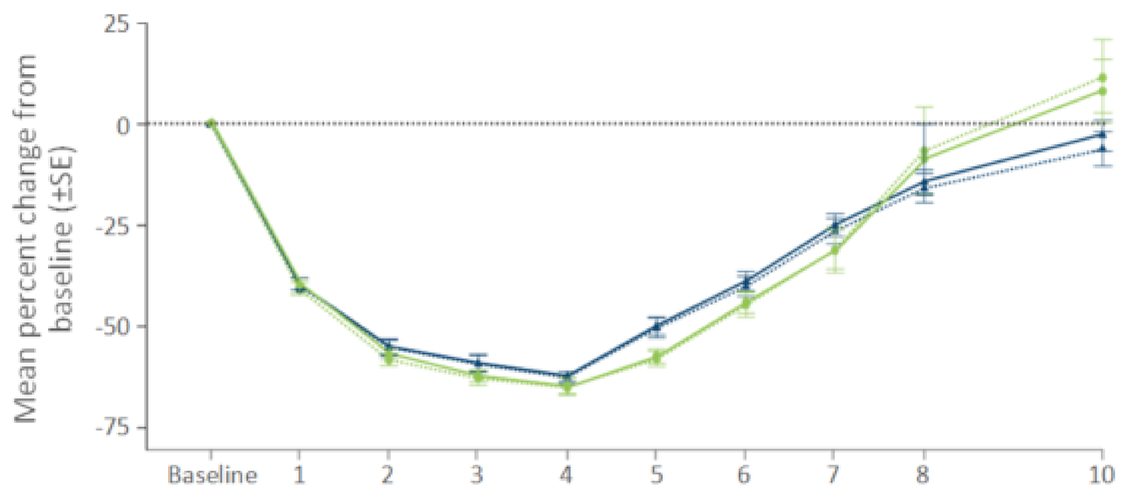
## RESULTS

### Primary Endpoint of Noninferiority Between Efgartigimod PH20 SC and Efgartigimod IV in Total IgG (%) Reduction at Day 29 Was Met

**Change (%) from Baseline in Total IgG Levels at Day 29 (primary endpoint; overall and AChR-Ab+ populations)**




**Change (%) from Baseline Over Time in Total IgG Level (overall and AChR-Ab+ populations)**

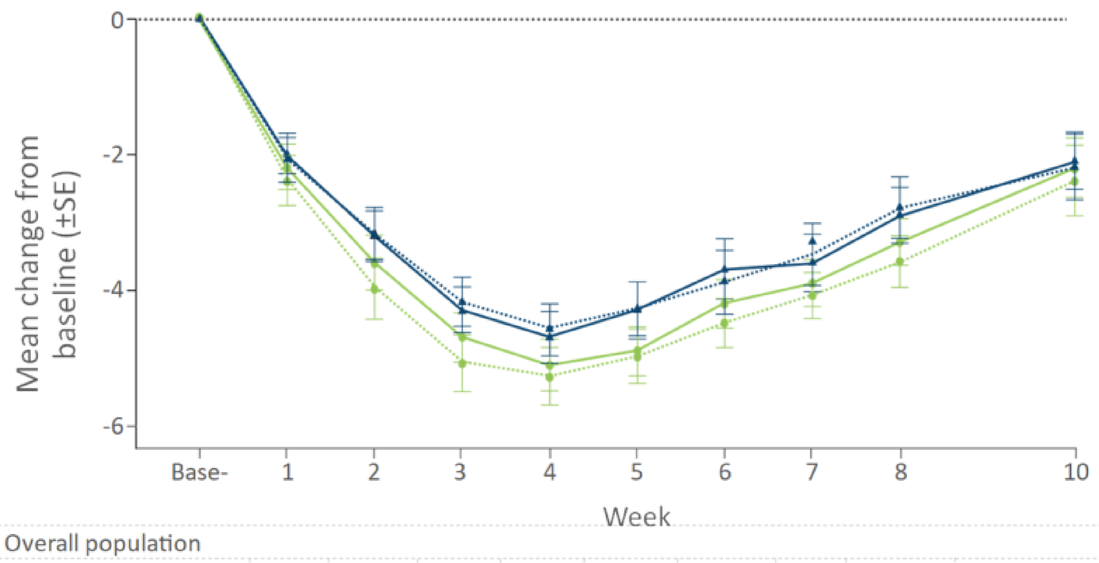



| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Overall population | | | | | | | | | |
| EFG PH20 SC | 52 | 53 | 52 | 53 | 53 | 49 | 52 | 54 | 54 |
| EFG IV | 55 | 55 | 55 | 52 | 52 | 50 | 52 | 54 | 54 |
| AChR-Ab+ population | | | | | | | | | |
| EFG PH20 SC | 43 | 43 | 42 | 44 | 43 | 39 | 42 | 44 | 44 |
| EFG IV | 46 | 46 | 46 | 43 | 44 | 42 | 44 | 45 | 45 |

## RESULTS

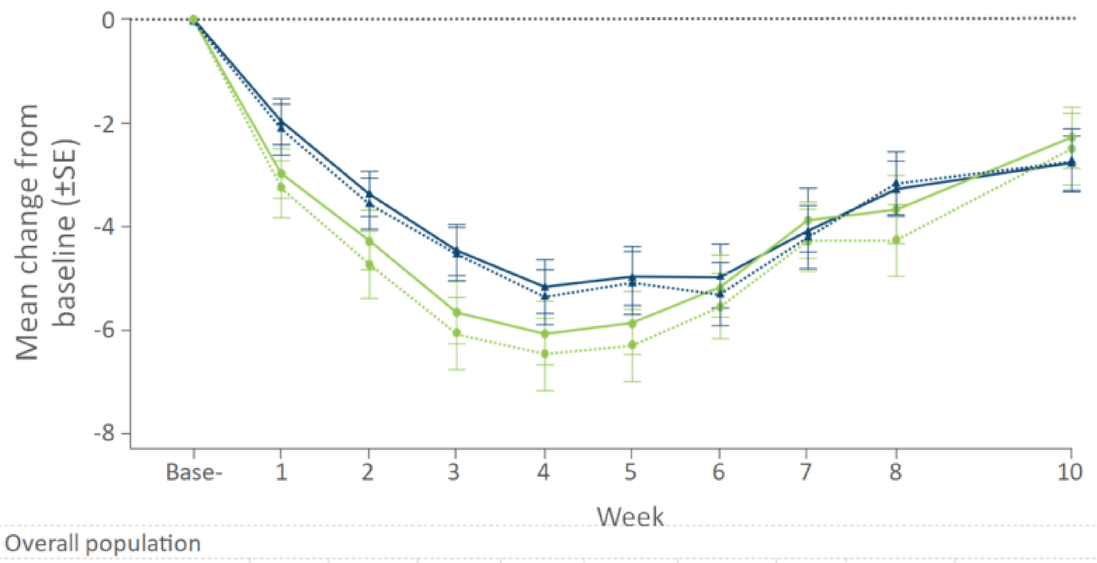
### Similar Effects Across the Multiple Efficacy Endpoints Were Reported for Both Efgartigimod PH20 SC and Efgartigimod IV

**MG-ADL Total Score Change from Baseline Over Time (overall and AChR-Ab+ populations)**




| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Overall population | | | | | | | | | |
| EFG PH20 SC | 53 | 54 | 51 | 52 | 53 | 50 | 50 | 46 | 46 |
| EFG IV | 55 | 55 | 55 | 53 | 53 | 52 | 51 | 50 | 51 |
| AChR-Ab+ population | | | | | | | | | |
| EFG PH20 SC | 44 | 44 | 41 | 43 | 43 | 40 | 40 | 36 | 37 |
| EFG IV | 46 | 46 | 46 | 44 | 45 | 44 | 43 | 42 | 42 |

**QMG Total Score Change from Baseline Over Time (overall and AChR-Ab+ populations)**




| | | | | | | | | | |
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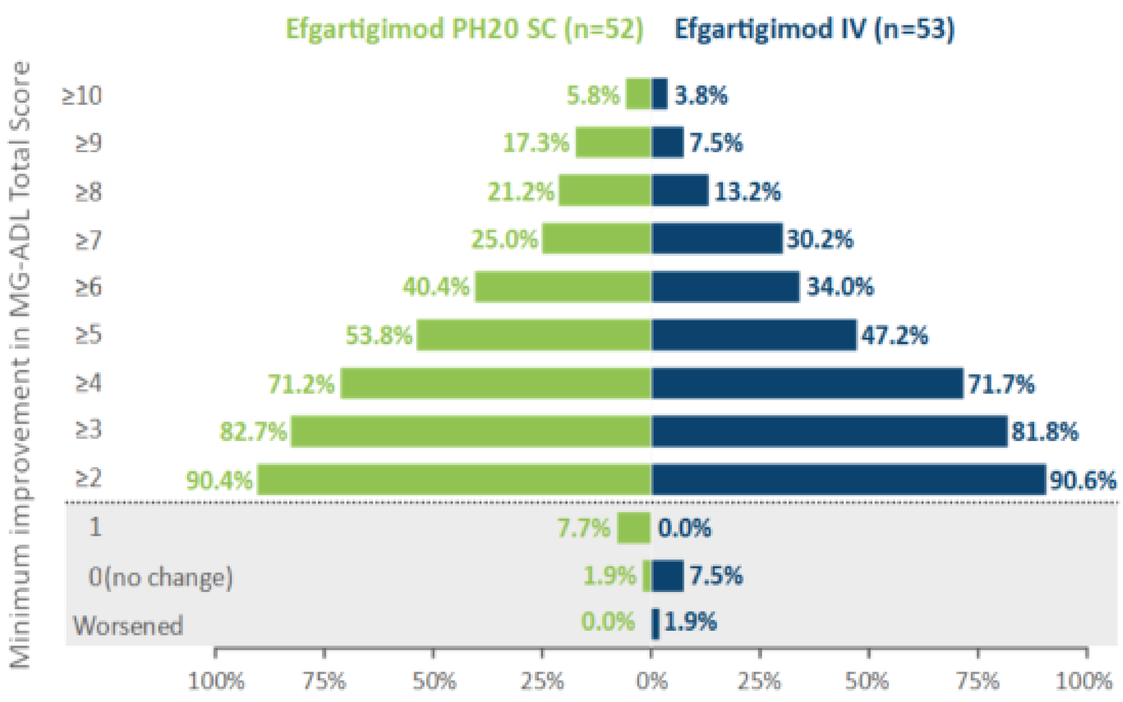
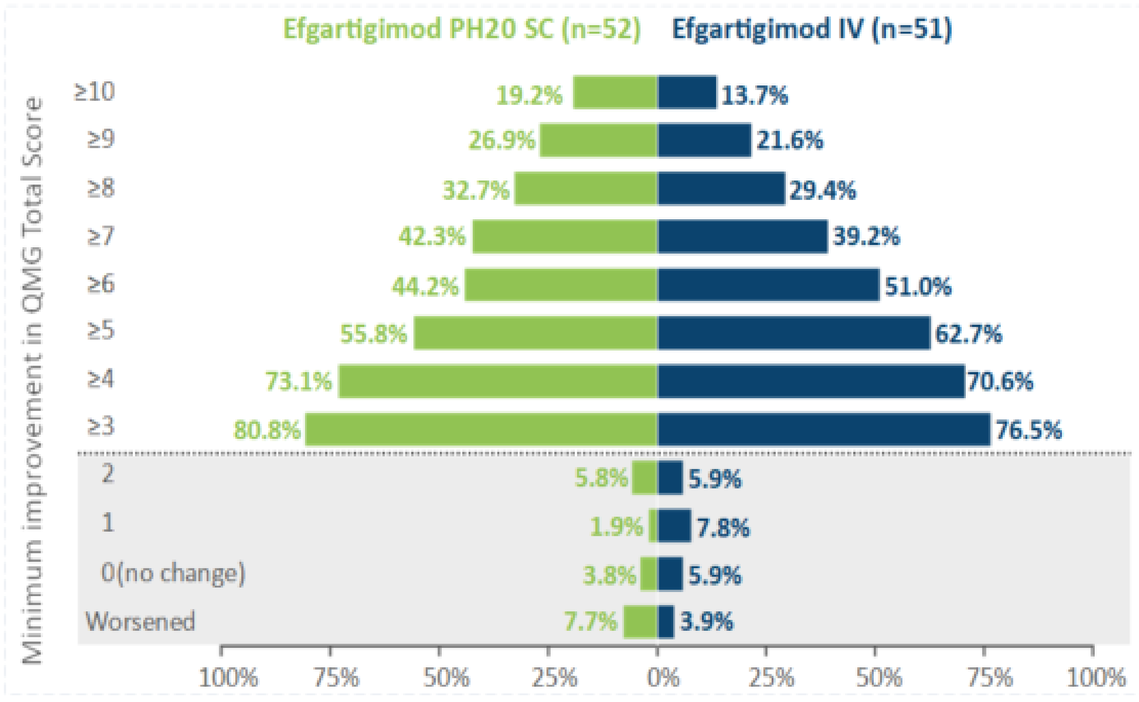
# RESULTS

## Change in MG-ADL Total Score at Week 4 (overall population)

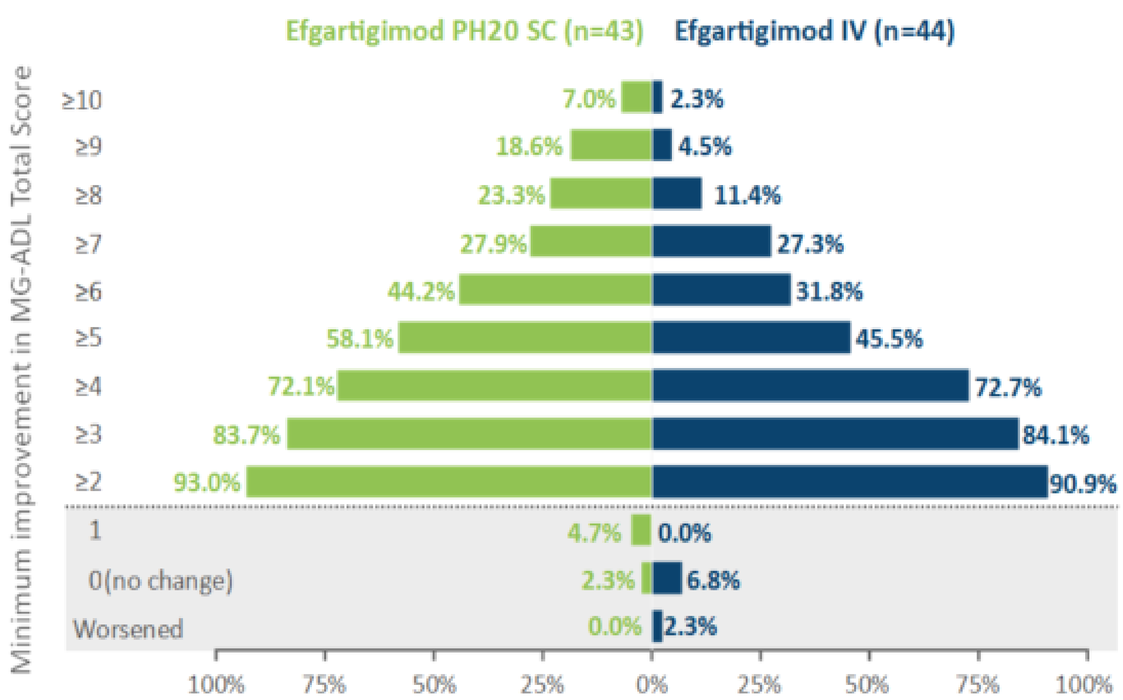



## Change in QMG Total Score at Week 4 (overall population)

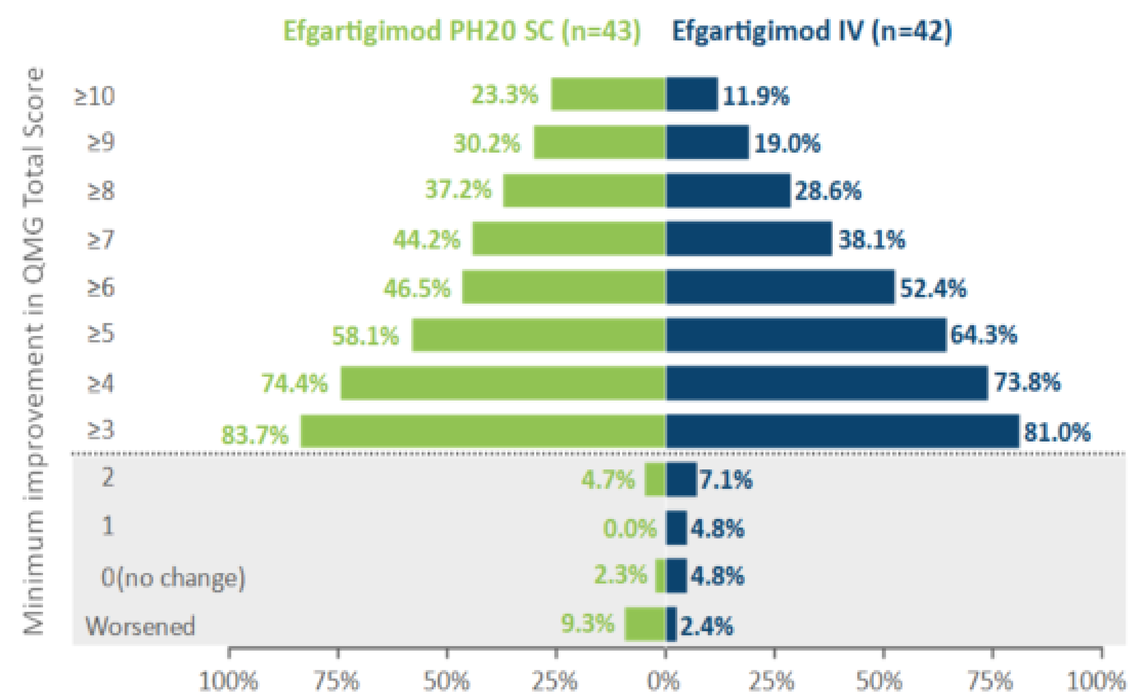



Scores above dashed line indicate clinically meaningful improvement. Minimum improvements 1 week after the last infusion of cycle 1 (week 4).

## Change in MG-ADL Total Score at Week 4 (AChR-Ab+ population)




## Change in QMG Total Score at Week 4 (AChR-Ab+ population)




Scores above dashed line indicate clinically meaningful improvement. Minimum improvements 1 week after the last infusion of cycle 1 (week 4).

# RESULTS

## Summary of Adverse Events

| | Efgartigimod PH20 SC (n=55) | Efgartigimod IV (n=55) |
|---|---|---|
| **Any AE**, n (%) | 37 (67.3) | 28 (50.9) |
| **Any AE Grade ≥3**, n (%) | 9 (16.4) | 4 (7.3) |
| **Any SAE**, n (%) | 8 (14.5) | 4 (7.3) |
| **≥1 injection-site reaction (localized)**, n (%) | 21 (38.2) | 1 (1.8)[a] |
| **Any infection**, n (%) | 10 (18.2) | 9 (16.4) |
| **Discontinued study treatment due to AEs**, n (%) | 2 (3.6)[b] | 0 (0.0) |
| **Most frequent AEs occurring in ≥5 patients**, n (%) | | |
| Injection site rash | 8 (14.5) | 0 (0) |
| Headache | 7 (12.7) | 7 (12.7) |
| Injection site erythema | 7 (12.7) | 0 (0) |
| Myasthenia gravis worsening | 6 (10.9) | 1 (1.8) |
| Injection site pruritus | 5 (9.1) | 0 (0) |
| Fatigue | 2 (3.6) | 3 (5.5) |

No Grade 5 or 4 AEs reported. [a]No preferred term AEs of injection-site reaction recorded. This AE was incorrectly coded (should have been catheter site reaction). [b]1 treatment discontinuation due to COVID-19 infection on Day 3 and the other due to MG worsening on Day 1.

- Efgartigimod was generally well tolerated
- Injection-site reactions were mild (18/21 patients) or moderate (3/21 patients) and most (19/21 patients) were transient and resolved without treatment
- Worsening of gMG symptoms typically happened at the end of the follow-up period. All patients who rolled over to the open-label extension had clinically meaningful improvement in MG-ADL when they received efgartigimod again

## SUMMARY

The primary endpoint was met for noninferiority of efgartigimod PH20 SC 1000 mg to IV 10 mg/kg in terms of percent reduction from baseline in total IgG levels at Day 29, ie, 7 days after the fourth SC or IV administration

Safety and tolerability of efgartigimod PH20 SC was similar to efgartigimod IV, with the exception of injection-site reactions, which were all mild-to-moderate in severity and did not lead to treatment discontinuation

**ABBREVIATIONS:** AChEI, acetylcholinesterase inhibitor; AChR-Ab, acetylcholine receptor antibody; AE, adverse event; EFG, efgartigimod; FcRn, neonatal Fc receptor; gMG, generalized myasthenia gravis; IgG, immunoglobulin G; IV, intravenous; MG-ADL, Myasthenia Gravis Activities of Daily Living; MGFA, Myasthenia Gravis Foundation of America; NSIST, nonsteroidal immunosuppressive therapy; PH20, recombinant human hyaluronidase PH20; QMG, Quantitative Myasthenia Gravis; SAE, serious adverse event; SC, subcutaneous; SE, standard error.

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