VYVGART® (efgartigimod alfa-fcab)
Injection for Intravenous Use
400 mg/20 mL vial

VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

Patient portrayals

VYVGART and VYVGART Hytrulo overview

Clinical data for 2 routes of administration[1,2]

The **first and only** IgG Fc-antibody fragment for the treatment of anti-AChR antibody positive gMG in adult patients[1-3]

AChR=acetylcholine receptor; Fc=fragment, crystallized; gMG=generalized myasthenia gravis; IgG=immunoglobulin G.

INDICATION

VYVGART® (efgartigimod alfa-fcab) for intravenous infusion and VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection are each indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

IMPORTANT SAFETY INFORMATION

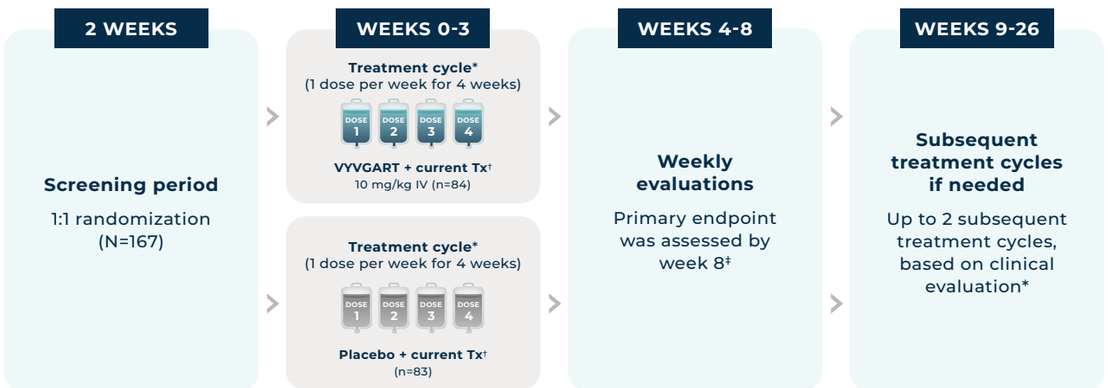
CONTRAINDICATIONS

VYVGART and VYVGART HYTRULO are contraindicated in patients with serious hypersensitivity to efgartigimod alfa products or to any of the excipients of VYVGART or VYVGART HYTRULO, respectively. VYVGART HYTRULO is also contraindicated in patients with serious hypersensitivity to hyaluronidase. Reactions have included anaphylaxis and hypotension leading to syncope.

Please see additional Important Safety Information throughout, full Prescribing Information for VYVGART, and full Prescribing Information for VYVGART Hytrulo.

The ADAPT phase 3 clinical trial[1,4]

A 26-week, multicenter, randomized, double-blind, placebo-controlled trial in 167 adult patients with gMG



The majority of patients (n=65 for **VYVGART**; n=64 for placebo) were positive for AChR antibodies.†

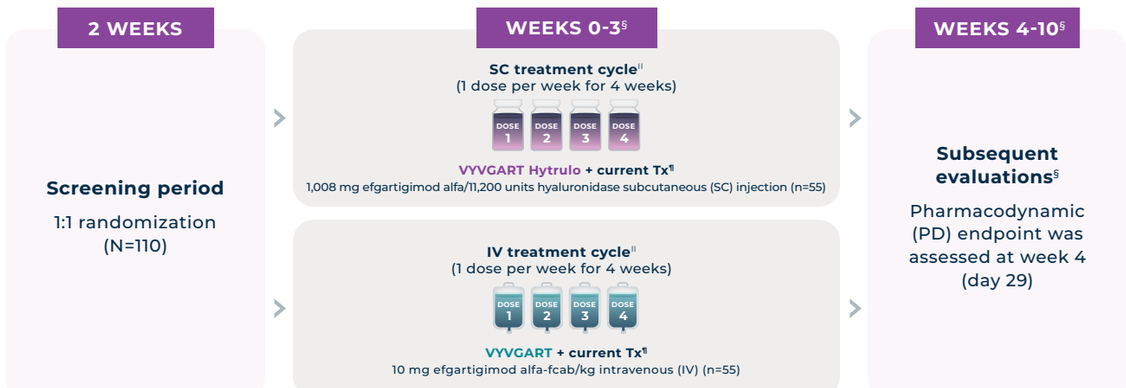
*All patients received an initial cycle, with subsequent cycles administered based on individual clinical evaluation when their MG-ADL score was at least 5 (with >50% MG-ADL nonocular) and if the patient was an MG-ADL responder, when they no longer had a clinically meaningful decrease (defined as having a ≥2-point improvement in total MG-ADL score) compared to baseline. The minimum time between treatment cycles, specified by study protocol, was 4 weeks from the last infusion. A maximum of 3 cycles were possible in the 26-week study.
†All patients received stable doses of their current gMG treatment.
‡Primary endpoint: the percentage of anti-AChR antibody positive patients who were MG-ADL responders, defined as a ≥2-point reduction in the total MG-ADL score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.
AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; MG-ADL=Myasthenia Gravis Activities of Daily Living; Tx=treatment.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS
Infection

VYVGART and VYVGART HYTRULO may increase the risk of infection. The most common infections observed in Study 1 were urinary tract infection (10% of efgartigimod alfa-fcab-treated patients vs 5% of placebo-treated patients) and respiratory tract infection (33% of efgartigimod alfa-fcab-treated patients vs 29% of placebo-treated patients).

The ADAPT-SC phase 3 clinical trial[2,5-7]

A 10-week, phase 3, multicenter, randomized, open-label, parallel-group trial in 110 adult patients with gMG



- The pharmacological effect of **VYVGART Hytrulo** administered subcutaneously was compared to **VYVGART** administered intravenously in adult patients with gMG
- Efficacy of **VYVGART Hytrulo** is based on this pharmacodynamic bridging study, which assessed the decrease in AChR-autoantibody levels
- The majority of patients (n=91) were positive for AChR antibodies
- In addition to pharmacodynamics, safety of **VYVGART Hytrulo** was also assessed
- Eligible patients were able to enter the open-label extension ADAPT-SC+ trial

§Patients were evaluated weekly from weeks 1-8, and then at week 10.
‖MG-ADL total score of ≥5 required at screening with >50% of the total score attributed to nonocular symptoms.
¶All patients received stable doses of their current gMG treatment.

IMPORTANT SAFETY INFORMATION (cont'd)
Infection (cont'd)

Patients on efgartigimod alfa-fcab vs placebo had below normal levels for white blood cell counts (12% vs 5%, respectively), lymphocyte counts (28% vs 19%, respectively), and neutrophil counts (13% vs 6%, respectively).

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ADAPT represented a range of adult patients with gMG[1,4,7]

167 patients

Mean age: 46 (VYVGART) vs 48 (placebo)
Female: 75% (VYVGART) vs 66% (placebo)
Anti-AChR antibody positive: n=65/84 (VYVGART) vs n=64/83 (placebo)

9 mean baseline (MG-ADL SCORE; BOTH ARMS)*

- MG-ADL 5-7: **24% (VYVGART) vs 27% (placebo)†**
- MG-ADL 8-9: **37% (VYVGART) vs 41% (placebo)†**
- MG-ADL ≥10: **39% (VYVGART) vs 33% (placebo)†**

(0=normal; 24=most severe)

16 mean baseline (QMG SCORE; BOTH ARMS)

QMG **Range: 4-28 (overall)**
(0=normal; 39=most severe)

Patients should be advised to complete age-appropriate vaccines according to immunization guidelines prior to initiation of a new treatment cycle with VYVGART. Vaccination with live-attenuated or live vaccines is not recommended during treatment with VYVGART. No specific vaccinations were required in the ADAPT clinical trial inclusion criteria.

*MG-ADL total score of ≥5 required at screening.
†Sum of the percentages is over 100% due to rounding.
‡Conditions shown represent the 5 most prevalent comorbidities reported by investigator at baseline in the ADAPT clinical trial (N=167).
AChE=acetylcholinesterase; AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; MG-ADL=Myasthenia Gravis Activities of Daily Living; MGFA=Myasthenia Gravis Foundation of America; NSIST=nonsteroidal immunosuppressive therapy; QMG=Quantitative Myasthenia Gravis.

MGFA class at screening:

- **40%** in the VYVGART arm had **mild** disease (MGFA class II) vs **37%** placebo
- **56%** in the VYVGART arm had **moderate** disease (MGFA class III) vs **59%** placebo
- **4%** in the VYVGART arm had **severe** disease (MGFA class IV) vs **4%** placebo

gMG treatments at study entry (in each arm):

- **~60%** NSISTs
- **>70%** Steroids
- **>80%** AChE inhibitors

5 most prevalent comorbidities at baseline (overall population)‡:

- **Hypertension: 28%**
- **Depression: 13%**
- **Diabetes Mellitus: 10%**
- **Osteoporosis: 9%**
- **Gastroesophageal Reflux Disease: 9%**

Patients who had active hepatitis B, were seropositive for hepatitis C, were seropositive for HIV with low CD4 count, had severe infections, or had evidence of any significant malignant disease were not eligible to participate in the ADAPT trial.

IMPORTANT SAFETY INFORMATION (cont'd)
Infection (cont'd)
The majority of infections and hematologic abnormalities were mild to moderate in severity. Delay the administration of VYVGART or VYVGART HYTRULO in patients with an active infection until the infection has resolved; monitor for clinical signs and symptoms of infections.

ADAPT-SC represented a range of adult patients with gMG[5,7]

VYVGART Hytrulo
VYVGART

110 patients

Mean age: 51 (VYVGART Hytrulo) vs 56 (VYVGART)
Female: 56% (VYVGART Hytrulo) vs 62% (VYVGART)
Anti-AChR antibody positive: n=45/55 (VYVGART Hytrulo) vs n=46/55 (VYVGART)

VYVGART Hytrulo 8.8 mean baseline MG-ADL score§
VYVGART 8.5 mean baseline MG-ADL score§

- MG-ADL 5-7: **36% (VYVGART Hytrulo) vs 44%‖ (VYVGART)**
- MG-ADL 8-9: **29% (VYVGART Hytrulo) vs 22%‖ (VYVGART)**
- MG-ADL ≥10: **35% (VYVGART Hytrulo) vs 35%‖ (VYVGART)**

(0=normal; 24=most severe)

VYVGART Hytrulo 14.9 mean baseline QMG score
VYVGART 15.5 mean baseline QMG score

QMG
(0=normal; 39=most severe)

MGFA CLASS AT SCREENING

53%‖ in the **VYVGART Hytrulo** arm had mild disease (MGFA class II) vs **40% VYVGART**
44%‖ in the **VYVGART Hytrulo** arm had moderate disease (MGFA class III) vs **55% VYVGART**
4%‖ in the **VYVGART Hytrulo** arm had severe disease (MGFA class IV) vs **5% VYVGART**

gMG TREATMENTS AT STUDY ENTRY (each arm)

AChE inhibitors (>85%), steroids (≥60%), NSISTs (>40%)

§MG-ADL total score of ≥5 required at screening.
‖Sum of the percentages is over 100% due to rounding.

IMPORTANT SAFETY INFORMATION (cont'd)
Infection (cont'd)
If serious infection occurs, administer appropriate treatment and consider withholding treatment with VYVGART or VYVGART HYTRULO until the infection has resolved.

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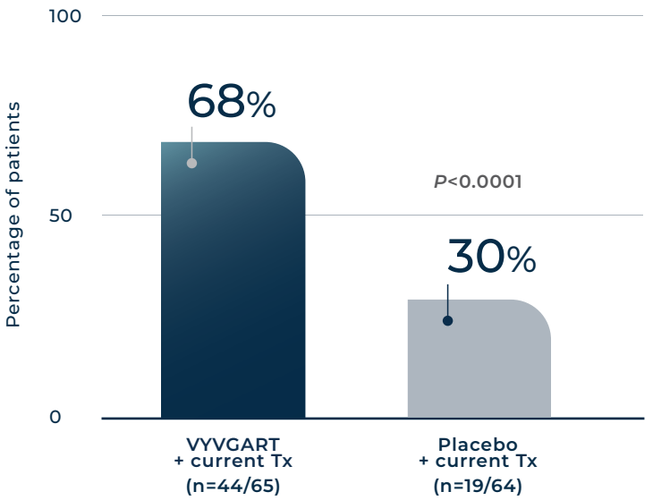
>2x as many patients had improvement in daily function sustained for ≥4 weeks during the first treatment cycle[1,4]

PRIMARY ENDPOINT

≥2 POINT REDUCTION in MG-ADL score from baseline **for at least 4 consecutive weeks** during the first treatment cycle



MG-ADL responders (First treatment cycle)

The primary endpoint was the percentage of anti-AChR antibody positive patients who were MG-ADL responders, defined as a patient with a ≥2-point reduction in the total MG-ADL score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.

AChR=acetylcholine receptor; MG-ADL=Myasthenia Gravis Activities of Daily Living; Tx=treatment.

IMPORTANT SAFETY INFORMATION (cont'd)
Immunization

Immunization with vaccines during treatment with VYVGART or VYVGART HYTRULO has not been studied; the safety with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because VYVGART and VYVGART HYTRULO cause a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during treatment with VYVGART or VYVGART HYTRULO.

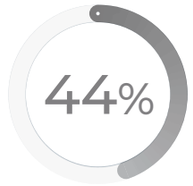
Post-hoc analysis: MG-ADL response data across first or second treatment cycles[4,7]*

POST-HOC ANALYSIS

Observed across the first or second treatment cycles:

of **VYVGART**-treated patients (n=51/65) had an MG-ADL response

vs



of **placebo**-treated patients (n=28/64) had an MG-ADL response

44/65 patients treated with VYVGART had a response during the first treatment cycle vs 19/64 treated with placebo. Of the 21 patients treated with VYVGART who did not have a response during the first treatment cycle, 7 were responders during the second treatment cycle. Of the 45 patients treated with placebo who did not have a response during the first treatment cycle, 9 were responders during the second treatment cycle[†‡]

Study Limitations: a post-hoc analysis based on a prespecified descriptive exploratory endpoint not controlled for multiplicity and not powered; therefore, data should be interpreted with caution and conclusions cannot be drawn.

*Clinical trial data from patients who were anti-AChR antibody positive. Patients were treated with VYVGART + current treatment or placebo + current treatment.
†MG-ADL response was defined as a ≥2-point reduction in the total MG-ADL score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.
‡The same measure for response was applied to the analysis during the second treatment cycle.

IMPORTANT SAFETY INFORMATION (cont'd)
Immunization (cont'd)

Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART or VYVGART HYTRULO.

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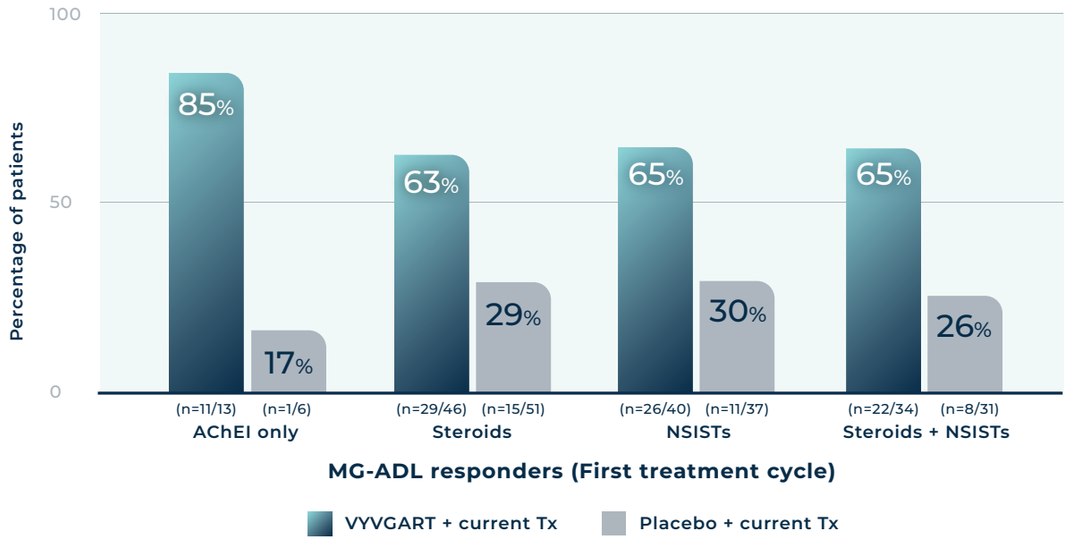
Post-hoc analysis: MG-ADL response data during the first treatment cycle across current therapies[1,8*†]

POST-HOC ANALYSIS



Study Limitations: a post-hoc analysis not controlled for multiplicity and not powered; therefore, data should be interpreted with caution and conclusions cannot be drawn. The analysis is based on limited sample size and follow-up per patient duration. Patients may have been taking different treatments for gMG simultaneously, therefore some patients may have been counted multiple times across subgroups.

*MG-ADL response was defined as a ≥2-point reduction in the total MG-ADL score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.
†Clinical trial data for anti-AChR antibody positive patients. Patients were treated with VYVGART + current treatment or placebo + current treatment. Patients were required to be on a stable dose of at least 1 treatment for gMG (ie, AChEIs, corticosteroids, or NSISTs) before screening and throughout the trial.
AChEI=acetylcholinesterase inhibitor; AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; MG-ADL=Myasthenia Gravis Activities of Daily Living; NSIST=nonsteroidal immunosuppressive therapy; Tx=treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART or VYVGART HYTRULO. Urticaria was also observed in patients treated with VYVGART HYTRULO. Hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation.

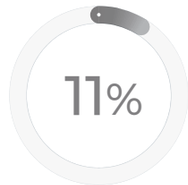
Exploratory endpoint: MG-ADL data for Minimal Symptom Expression (MSE)[1,4,7‡]

EXPLORATORY ENDPOINT

Observed during the first treatment cycle:

of patients on **VYVGART** + current Tx (n=26/65) had an MG-ADL score of 0 or 1 (MSE)

vs



of patients on **placebo** + current Tx (n=7/64) had an MG-ADL score of 0 or 1 (MSE)

Percentage of patients with MSE. MSE is characterized by an MG-ADL total score of 0 or 1 out of a maximum of 24. Patients were evaluated at any visit during the first treatment cycle[§]

Study Limitations: a prespecified descriptive exploratory analysis not controlled for multiplicity and not powered; therefore, data should be interpreted with caution and conclusions cannot be drawn.

‡Clinical trial data for anti-AChR antibody positive patients. Patients were treated with VYVGART + current treatment or placebo + current treatment.
§MSE evaluation occurred at any visit from week 1 through week 26.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions (cont'd)

Anaphylaxis and hypotension leading to syncope have been reported in postmarketing experience with intravenous efgartigimod alfa-fcab. Anaphylaxis and hypotension occurred during or within an hour of administration and led to infusion discontinuation and in some cases to permanent treatment discontinuation.

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Exploratory endpoint: early response data by week 2 during the first treatment cycle[7]*

EXPLORATORY ENDPOINT

of patients treated with **VYVGART** (n=37/44) who were MG-ADL responders showed a response by week 2 during the first treatment cycle. These patients were observed to be early responders†

of patients treated with **placebo** (n=16/19) who met the primary endpoint showed a response by week 2

Study Limitations: percentage of early responders (response by week 2) in anti-AChR antibody positive patients treated with VYVGART was a prespecified descriptive exploratory analysis not controlled for multiplicity and not powered; therefore, data should be interpreted with caution and conclusions cannot be drawn.

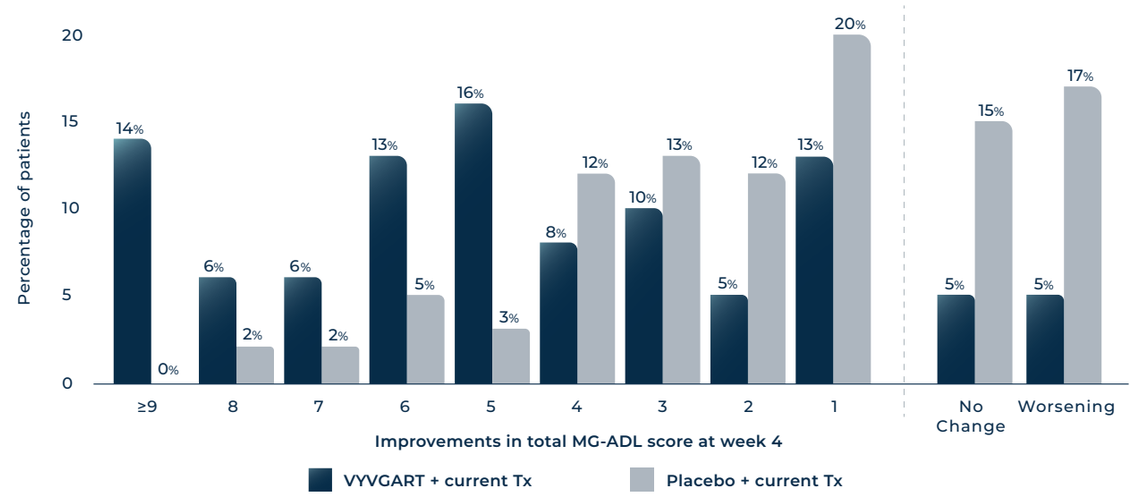
*Clinical trial data for anti-AChR antibody positive patients. Patients were treated with VYVGART + current treatment or placebo + current treatment.
†MG-ADL early response was defined as a ≥2-point reduction in the total MG-ADL score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the scheduled second infusion (week 2).
AChR=acetylcholine receptor; MG-ADL=Myasthenia Gravis Activities of Daily Living.

IMPORTANT SAFETY INFORMATION (cont'd)
Hypersensitivity Reactions (cont'd)

Healthcare professionals should monitor patients during and for 1 hour after VYVGART administration, or for at least 30 minutes after VYVGART HYTRULO administration, for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs, the healthcare professional should institute appropriate measures if needed or the patient should seek medical attention.

Improvement in daily function at week 4 during the first treatment cycle[1,4‡§]

- **≥9-point reduction** in **14%** of patients with **VYVGART** vs **0%** with placebo
- **≥5-point reduction** in **55%** of patients with **VYVGART** vs **12%** with placebo



‡Clinical trial data for anti-AChR antibody positive patients. Patients were treated with VYVGART + current treatment or placebo + current treatment.
§Four weeks after the initial infusion of the first treatment cycle.
Tx=treatment.

IMPORTANT SAFETY INFORMATION (cont'd)
Infusion-Related Reactions

Infusion-related reactions have been reported with intravenous efgartigimod alfa-fcab in postmarketing experience.

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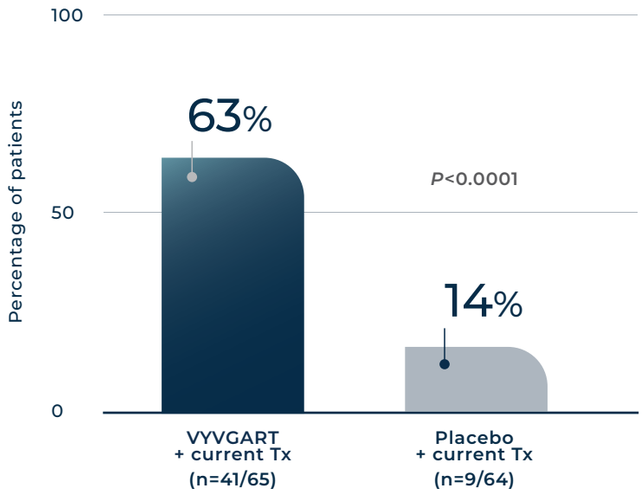
>4x as many patients had reduction in muscle weakness sustained for ≥4 weeks during the first treatment cycle[1,4]

Comparable pharmacodynamic effect for VYVGART Hytrulo[2,7*†]

SECONDARY ENDPOINT

≥3 POINT REDUCTION in QMG score from baseline **for at least 4 consecutive weeks** during the first treatment cycle



QMG responders (First treatment cycle)

The secondary endpoint was the percentage of anti-AChR antibody positive patients who were QMG responders, defined as a patient with a ≥3-point reduction in the total QMG score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.

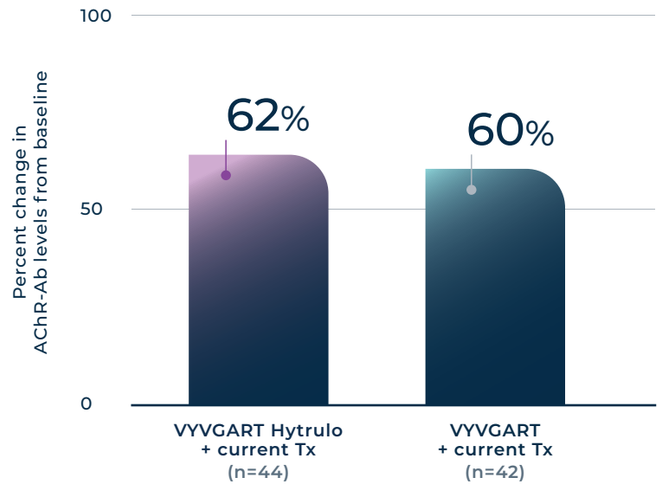
AChR=acetylcholine receptor; QMG=Quantitative Myasthenia Gravis; Tx=treatment.

IMPORTANT SAFETY INFORMATION (cont'd)
Infusion-Related Reactions (cont'd)

The most frequent symptoms and signs were hypertension, chills, shivering, and thoracic, abdominal, and back pain. Infusion-related reactions occurred during or within an hour of administration and led to infusion discontinuation. If a severe infusion-related reaction occurs during administration, discontinue VYVGART infusion and initiate appropriate therapy. If a severe infusion-related reaction occurs with VYVGART HYTRULO, initiate appropriate therapy. Consider the risks and benefits of readministering VYVGART or VYVGART HYTRULO following a severe infusion-related reaction.

PD ENDPOINT

Reduction of AChR-Ab levels at week 4 vs VYVGART



PD effect of **VYVGART Hytrulo** and **VYVGART** in percent reduction from baseline in AChR-Ab levels at week 4 (day 29) in the anti-AChR antibody positive population.‡

The maximum mean reduction in AChR-Ab levels was observed at week 4.

The decrease in total IgG levels followed a similar pattern.

*The 90% confidence interval for the geometric mean ratios of AChR-Ab reduction at day 29 and $AUEC_{0\text{-}4w}$ (area under the effect-time curve from time 0 to 4 weeks post dose) were within the range of 80% to 125%, indicating no clinically significant difference between the two formulations.
†Clinical trial data for anti-AChR antibody positive patients.
‡Seven days after the fourth IV or SC administration.
AChR-Ab=acetylcholine receptor antibody; IgG=immunoglobulin G; IV=intravenous; PD=pharmacodynamic; SC=subcutaneous.

IMPORTANT SAFETY INFORMATION (cont'd)
Infusion-Related Reactions (cont'd)

If a mild to moderate infusion-related reaction occurs, patients may be rechallenged with close clinical observation, slower infusion rates, and pre-medications.

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Demonstrated safety profile in the ADAPT clinical trial[1]

Adverse reactions in ≥5% of patients treated with VYVGART and more frequently than placebo in ADAPT

ADVERSE REACTION	VYVGART (n=84)	Placebo (n=83)
Respiratory tract infection	**33%**	**29%**
Headache*	**32%**	**29%**
Urinary tract infection	**10%**	**5%**
Paraesthesia†	**7%**	**5%**
Myalgia	**6%**	**1%**

*Headache includes migraine and procedural headache.
†Paraesthesia includes oral hypoesthesia, hypoesthesia, and hyperesthesia.

A higher frequency of patients who received **VYVGART** compared to placebo were observed to have below normal levels of white blood cell counts (12% vs 5%), lymphocyte counts (28% vs 19%), and neutrophil counts (13% vs 6%).

The majority of infections and hematologic abnormalities were mild to moderate in severity.

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in **VYVGART**-treated patients. Hypersensitivity reactions were mild or moderate, occurred within one hour to three weeks of administration, and did not lead to treatment discontinuation.

Postmarketing experience with **VYVGART** included reports of anaphylaxis and hypotension leading to syncope, as well as infusion-related reactions including hypertension, chills, shivering, and thoracic, abdominal, and back pain. These reactions occurred during or within an hour of administration and led to infusion discontinuation and in some cases to permanent treatment discontinuation.

IMPORTANT SAFETY INFORMATION (cont'd)
ADVERSE REACTIONS

In Study 1, the most common (≥10%) adverse reactions in efgartigimod alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. In Study 2, the most common (≥10%) adverse reactions in VYVGART HYTRULO-treated patients were injection site reactions and headache.

A consistent safety profile in the ADAPT-SC clinical trial[1,2,9]

The overall safety profile of VYVGART Hytrulo, except for a higher rate of injection site reactions, was consistent with the proven safety profile of VYVGART

In ADAPT-SC, injection site reactions occurred in 38% of patients receiving **VYVGART Hytrulo**. These were injection site rash, erythema, pruritus, bruising, pain, and urticaria.

In ADAPT-SC and its open-label extension (n=168):

- Injection site reactions were mild to moderate in severity and did not lead to treatment discontinuation
- The majority occurred within 24 hours after administration and resolved spontaneously
- Most injection site reactions occurred during the first treatment cycle, and the incidence of injection site reactions decreased with each subsequent cycle
    - Cycle 1: 34.1% (n=56); cycle 2: 16.9% (n=24); cycle 3: 13.3% (n=14); and cycle 4: 11.8% (n=8)‡

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with **VYVGART Hytrulo** or **VYVGART**. Urticaria was also observed in patients treated with **VYVGART Hytrulo**. Hypersensitivity reactions were mild or moderate, occurred within one hour to three weeks of administration, and did not lead to treatment discontinuation.

Postmarketing experience with **VYVGART** included reports of anaphylaxis and hypotension leading to syncope, as well as infusion-related reactions including hypertension, chills, shivering, and thoracic, abdominal, and back pain. These reactions occurred during or within an hour of administration and led to infusion discontinuation and in some cases to permanent treatment discontinuation.

‡Interim results presented April 2023. The ADAPT-SC+ Open-label Extension study is still ongoing.

IMPORTANT SAFETY INFORMATION (cont'd)
ADVERSE REACTIONS (cont'd)

Injection site reactions occurred in 38% of VYVGART HYTRULO-treated patients, including injection site rash, erythema, pruritus, bruising, pain, and urticaria.

Please see additional Important Safety Information throughout, full Prescribing Information for VYVGART, and full Prescribing Information for VYVGART Hytrulo.

VYVGART® (efgartigimod alfa-fcab)
Injection for Intravenous Use
400 mg/20 mL vial

VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

VYVGART and VYVGART Hytrulo: 2 options for ongoing treatment for effective symptom management[1,2]*

Recommended dose and dose schedules from Prescribing Information:

VYVGART: **1 TREATMENT CYCLE**[1]

1-HOUR IV INFUSION
PER WEEK **FOR 4 WEEKS**
(10 mg efgartigimod alfa-fcab/kg) (weight-based)†

VYVGART HYTRULO: **1 TREATMENT CYCLE**[2]

~30-90-SECOND SC INJECTION‡
PER WEEK **FOR 4 WEEKS**
(1,008 mg efgartigimod alfa/ 11,200 units hyaluronidase) (fixed dose)

The recommended dose of **VYVGART** (efgartigimod alfa-fcab) is 10 mg/kg, given in treatment cycles of once-weekly, 1-hour IV infusions for 4 weeks.§

The recommended dose of **VYVGART Hytrulo** is 1,008 mg/11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase), given in treatment cycles of once-weekly subcutaneous injections for 4 weeks.

Administer **subsequent treatment cycles** based on clinical evaluation[1,2]

Not actual size.

The safety of initiating subsequent cycles sooner than 4 weeks from the last infusion or injection of the previous treatment cycle has not been established.[1,2,4]

*MG-ADL response was defined as a ≥2-point reduction in total MG-ADL score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion or injection of the cycle.[1]
†In patients weighing 265 lbs (120 kg) or more, the recommended dose of VYVGART is 1,200 mg (3 vials) per infusion.[1]
‡Refers to actual injection time of VYVGART Hytrulo. Allow for appropriate storage, preparation, and setup time before use.[2]
§In the ADAPT phase 3 clinical trial, all patients received an initial cycle, with subsequent cycles administered according to individual clinical evaluation when their MG-ADL score was at least 5 (with >50% MG-ADL nonocular) and if the patient was an MG-ADL responder, when they no longer had a clinically meaningful decrease (defined as having a ≥2-point improvement in total MG-ADL score) compared to baseline. The minimum time between treatment cycles, specified by study protocol, was 4 weeks from the last infusion. A maximum of 3 cycles were possible in the 26-week study.[1,4]
IV=intravenous; MG-ADL=Myasthenia Gravis Activities of Daily Living; SC=subcutaneous.

IMPORTANT SAFETY INFORMATION (cont'd)
ADVERSE REACTIONS (cont'd)

In Study 2 and its open-label extension, all injection site reactions were mild to moderate in severity and did not lead to treatment discontinuation. The majority occurred within 24 hours after administration and resolved spontaneously.

An example approach: based on the most commonly observed schedule from a post-hoc analysis of ADAPT+ and ADAPT-SC+[7||¶]

CYCLES 1-3

4 WEEKS **ON** THERAPY

4 WEEKS **OFF** THERAPY#

FOR THE FIRST **3** TREATMENT CYCLES**

CYCLES 4+

+ **ADJUSTING TIME OFF THERAPY BASED ON CLINICAL EVALUATION**

For **cycles 1-3**, this example approach shows **4 weeks** on and **4 weeks** off therapy for 3 cycles.[7]

For subsequent cycles, **continue** evaluating the appropriate time off therapy based on clinical evaluation.[7]

Study Limitations: The distribution of average cycle duration in ADAPT+ and ADAPT-SC+ were post-hoc descriptive analyses not controlled for multiplicity and not powered; therefore, data should be interpreted with caution and conclusions cannot be drawn.

Ask an argenx representative about data from an exploratory phase 3B clinical trial studying this example approach[10]

||ADAPT+ and ADAPT-SC+ were single-arm, open-label studies evaluating the long-term safety and tolerability of VYVGART and VYVGART Hytrulo.[11,12]
¶Analysis included all complete cycles, defined as cycles not interrupted by the cut-off/final study date of December 1, 2022, or a single incomplete cycle of at least 28 days.[7]
#Four weeks off starts after the last infusion or injection of the most recent cycle.[7]
**A cycle consists of 4 once-weekly doses over 22 days.[7]

IMPORTANT SAFETY INFORMATION (cont'd)
ADVERSE REACTIONS (cont'd)

Most injection site reactions occurred during the first treatment cycle, and the incidence decreased with each subsequent cycle.

Please see additional Important Safety Information throughout, full Prescribing Information for VYVGART, and full Prescribing Information for VYVGART Hytrulo.

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Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

Considerations for starting treatment

- **MG-ADL assessments:** Share the MG-ADL scale and work with patients to get their baseline score
- **Patient counseling information:** Discuss the risk of infections, hypersensitivity reactions, and infusion-related reactions associated with their treatment*
- **Sites of care:** Review options for administration to understand patient needs and preferences
- **No treatment-specific vaccinations required to begin treatment:** HCPs should evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with **VYVGART** or **VYVGART Hytrulo**[1,2†]
- **No REMS required:** **VYVGART** and **VYVGART Hytrulo** do not require any specific training or certification prior to starting treatment at this time
- **No routine lab monitoring required:** No routine lab monitoring requirements for patients during treatment with **VYVGART** or **VYVGART Hytrulo**. Continue to evaluate response and monitor patients for possible side effects‡
- **No Boxed Warning:** Please see the full Prescribing Information for **VYVGART** and **VYVGART Hytrulo** before starting patients on treatment

*Please also see the Patient Counseling Information in Section 17 of the Prescribing Information.
MG-ADL=Myasthenia Gravis Activities of Daily Living.

†In accordance with the recommendations found in Section 2.1 of the Prescribing Information.
‡Patients in the ADAPT and ADAPT-SC clinical trials were required to have IgG levels of at least 6 g/L at study entry. Please also see the Warnings and Precautions found in Section 5 of the Prescribing Information.
HCP=healthcare professional; IgG=immunoglobulin G; REMS=Risk Evaluation and Mitigation Strategy.

IMPORTANT SAFETY INFORMATION (cont'd)
USE IN SPECIFIC POPULATIONS
Pregnancy

As VYVGART and VYVGART HYTRULO are expected to reduce maternal IgG antibody levels, reduction in passive protection to the newborn is anticipated. Risks and benefits should be considered prior to administering live or live attenuated vaccines to infants exposed to VYVGART or VYVGART HYTRULO in utero.

Lactation

There is no information regarding the presence of efgartigimod alfa-fcab from administration of VYVGART, or efgartigimod alfa or hyaluronidase from administration of VYVGART HYTRULO, in human milk, the effects on the breastfed infant, or the effects on milk production.

IMPORTANT SAFETY INFORMATION (cont'd)
Lactation (cont'd)

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VYVGART or VYVGART HYTRULO, and any potential adverse effects on the breastfed infant from VYVGART or VYVGART HYTRULO or from the underlying maternal condition.

Please see the full Prescribing Information for VYVGART and the full Prescribing Information for VYVGART HYTRULO.

Please see additional Important Safety Information throughout, full Prescribing Information for VYVGART, and full Prescribing Information for VYVGART Hytrulo.

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Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

Broad access for your patients

VYVGART for IV infusion—the **#1** prescribed FDA-approved biologic treatment for adults with anti-AChR antibody positive gMG—is also available as **VYVGART Hytrulo** for SC injection*

>90% of commercial and Medicare insured patients have coverage for **VYVGART**†

- Medicare Part B covers medications for indications, which are FDA approved to label
- As with all commercial insurance plans, coverage for **VYVGART** and **VYVGART Hytrulo** will depend on the terms and conditions of your patient's insurance plan

>90% of US commercial and Medicare insured patients have coverage allowing for an initial authorization of **VYVGART** for at least 6 months

- This can allow for **multiple infusion cycles** with the **first prescription**†

~80% of commercial and Medicare insured patients have coverage for **VYVGART Hytrulo** with new policies being added monthly†

- >95% of these patients have no distinction in coverage requirements between **VYVGART** and **VYVGART Hytrulo**
- Coverage for **VYVGART** and **VYVGART Hytrulo** will depend on the terms and conditions of your patient's insurance plan

argenx has a network of national distributors, specialty pharmacies, and infusion partners, making it easier for appropriate patients to access VYVGART or VYVGART Hytrulo

*Based on IQVIA LAAD data from January to December 2023. Data is based on validated claims of VYVGART for IV infusion and other biologics that have been approved by the FDA for the treatment of adults with anti-AChR antibody positive gMG. All claims are associated with patients who received 2 confirmed diagnoses of anti-AChR antibody positive gMG. Patients who were prescribed more than one of the biologics in this data set were counted for each biologic prescribed.
†Policy Reporter data as of January 2024.
AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; IV=intravenous; LAAD=Longitudinal Access and Adjudication Data; SC=subcutaneous.

IMPORTANT SAFETY INFORMATION (cont'd)

You may report side effects to the US Food and Drug Administration by visiting http://www.fda.gov/medwatch or calling 1-800-FDA-1088. You may also report side effects to argenx US, Inc, at 1-833-argx411 (1-833-274-9411).

Personalized support during the treatment journey for you and your patients

The committed team of **Case Coordinators** and **Nurse Case Managers** at My VYVGART Path offers:

- **Patient-specific benefit verifications**, including confirming out-of-pocket costs and prior authorization requirements
- **Screening for commercial co-pay** and other financial assistance for eligible patients
- **Referrals** to local and national myasthenia gravis resources and organizations
- **Help in connecting you with your patient's health plan** denial and appeal processes§

My VYVGART® Path

Visit **MyPathEnroll.com** or call **1-833-697-2841** for more information and assistance

Help your patients save on their treatment

Eligible commercially insured patients may pay as little as $0 for their co-pay through the **VYVGART Co-pay Program**‖

Two ways to enroll your patients

- **Online Enrollment:** Fill out and submit the My VYVGART Path enrollment form online at MyPathEnroll.com
- **Enrollment via Fax:** Download the enrollment form and fax the completed document to 1-833-698-7284

§Field Reimbursement Managers are not part of My VYVGART Path, but are available to provide assistance to Case Coordinators, as needed.
‖Eligible commercially insured patients may pay as little as $0 for VYVGART or VYVGART Hytrulo and may receive a maximum benefit of $25,000 per calendar year for their eligible out-of-pocket costs for the drug and drug administration. Persons residing in MA and RI are not eligible for financial assistance related to administration costs. Please see full Terms and Conditions.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VYVGART and VYVGART HYTRULO are contraindicated in patients with serious hypersensitivity to efgartigimod alfa products or to any of the excipients of VYVGART or VYVGART HYTRULO, respectively.

Please see additional Important Safety Information throughout, full Prescribing Information for VYVGART, and full Prescribing Information for VYVGART Hytrulo.

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VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

VYVGART® (efgartigimod alfa-fcab) for intravenous infusion and VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection are each indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VYVGART and VYVGART HYTRULO are contraindicated in patients with serious hypersensitivity to efgartigimod alfa products or to any of the excipients of VYVGART or VYVGART HYTRULO, respectively. VYVGART HYTRULO is also contraindicated in patients with serious hypersensitivity to hyaluronidase. Reactions have included anaphylaxis and hypotension leading to syncope.

WARNINGS AND PRECAUTIONS

Infection

VYVGART and VYVGART HYTRULO may increase the risk of infection. The most common infections observed in Study 1 were urinary tract infection (10% of efgartigimod alfa-fcab-treated patients vs 5% of placebo-treated patients) and respiratory tract infection (33% of efgartigimod alfa-fcab-treated patients vs 29% of placebo-treated patients). Patients on efgartigimod alfa-fcab vs placebo had below normal levels for white blood cell counts (12% vs 5%, respectively), lymphocyte counts (28% vs 19%, respectively), and neutrophil counts (13% vs 6%, respectively). The majority of infections and hematologic abnormalities were mild to moderate in severity. Delay the administration of VYVGART or VYVGART HYTRULO in patients with an active infection until the infection has resolved; monitor for clinical signs and symptoms of infections. If serious infection occurs, administer appropriate treatment and consider withholding treatment with VYVGART or VYVGART HYTRULO until the infection has resolved.

Immunization

Immunization with vaccines during treatment with VYVGART or VYVGART HYTRULO has not been studied; the safety with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because VYVGART and VYVGART HYTRULO cause a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during treatment with VYVGART or VYVGART HYTRULO. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART or VYVGART HYTRULO.

Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART or VYVGART HYTRULO. Urticaria was also observed in patients treated with VYVGART HYTRULO. Hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation. Anaphylaxis and hypotension leading to syncope have been reported in postmarketing experience with intravenous efgartigimod alfa-fcab. Anaphylaxis and hypotension occurred during or within an hour of administration and led to infusion discontinuation and in some cases to permanent treatment discontinuation. Healthcare professionals should monitor patients during and for 1 hour after VYVGART administration, or for at least 30 minutes after VYVGART HYTRULO administration, for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs, the healthcare professional should institute appropriate measures if needed or the patient should seek medical attention.

Infusion-Related Reactions

Infusion-related reactions have been reported with intravenous efgartigimod alfa-fcab in postmarketing experience. The most frequent symptoms and signs were hypertension, chills, shivering, and thoracic, abdominal, and back pain. Infusion-related reactions occurred during or within an hour of administration and led to infusion discontinuation. If a severe infusion-related reaction occurs during administration, discontinue VYVGART infusion and initiate appropriate therapy. If a severe infusion-related reaction occurs with VYVGART HYTRULO, initiate appropriate therapy. Consider the risks and benefits of readministering VYVGART or VYVGART HYTRULO following a severe infusion-related reaction. If a mild to moderate infusion-related reaction occurs, patients may be rechallenged with close clinical observation, slower infusion rates, and pre-medications.

ADVERSE REACTIONS

In Study 1, the most common (≥10%) adverse reactions in efgartigimod alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. In Study 2, the most common (≥10%) adverse reactions in VYVGART HYTRULO-treated patients were injection site reactions and headache. Injection site reactions occurred in 38% of VYVGART HYTRULO-treated patients, including injection site rash, erythema, pruritus, bruising, pain, and urticaria. In Study 2 and its open-label extension, all injection site reactions were mild to moderate in severity and did not lead to treatment discontinuation. The majority occurred within 24 hours after administration and resolved spontaneously. Most injection site reactions occurred during the first treatment cycle, and the incidence decreased with each subsequent cycle.

USE IN SPECIFIC POPULATIONS

Pregnancy

As VYVGART and VYVGART HYTRULO are expected to reduce maternal IgG antibody levels, reduction in passive protection to the newborn is anticipated. Risks and benefits should be considered prior to administering live or live attenuated vaccines to infants exposed to VYVGART or VYVGART HYTRULO in utero.

Lactation

There is no information regarding the presence of efgartigimod alfa-fcab from administration of VYVGART, or efgartigimod alfa or hyaluronidase from administration of VYVGART HYTRULO, in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VYVGART or VYVGART HYTRULO, and any potential adverse effects on the breastfed infant from VYVGART or VYVGART HYTRULO or from the underlying maternal condition.

Please see the full Prescribing Information for VYVGART and the full Prescribing Information for VYVGART HYTRULO.

You may report side effects to the US Food and Drug Administration by visiting http://www.fda.gov/medwatch or calling 1-800-FDA-1088. You may also report side effects to argenx US, Inc, at 1-833-argx411 (1-833-274-9411).

References: 1. VYVGART. Prescribing information. argenx US Inc; 2024. **2.** VYVGART Hytrulo. Prescribing information. argenx US Inc; 2024. **3.** Wolfe GI et al. *J Neurol Sci*. 2021;430:118074. doi:10.1016/j.jns.2021.118074 **4.** Howard JF Jr et al. *Lancet Neurol*. 2021;20(7):526-536. doi:10.1016/S1474-4422(21)00159-9 **5.** Casey J et al. Poster presented at: 27th International Hybrid Annual Congress of the World Muscle Society; October 2022. Halifax, Nova Scotia, Canada. **6.** ClinicalTrials.gov. NCT04735432. Accessed June 5, 2024. https://clinicaltrials.gov/ct2/show/NCT04735432 **7.** Data on file, argenx US Inc. August 2024. **8.** Karam C et al. Presented at: Myasthenia Gravis Foundation of America (MGFA) National Conference; April 11-13, 2021. Canada. Virtual. **9.** Howard JF Jr et al. Poster presented at: American Academy of Neurology (AAN) Annual Meeting; April 22-27, 2023. Boston, MA. **10.** Bril V et al. Presented at: American Academy of Neurologists (AAN) Annual Meeting; April 13-18, 2024. Denver, CO and virtual. **11.** ClinicalTrials.gov. NCT03770403. Accessed June 5, 2024. https://clinicaltrials.gov/study/NCT03770403 **12.** ClinicalTrials gov. NCT04818671. Accessed June 5, 2024. https://clinicaltrials.gov/study/NCT04818671

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Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

Two routes to efficacy and safety for adult patients with anti-AChR antibody positive gMG[1,2]

DEMONSTRATED EFFICACY AND SAFETY

- **VYVGART** improved daily function (MG-ADL) and reduced muscle weakness (QMG) during the first treatment cycle*†
- **VYVGART Hytrulo** demonstrated a similar pharmacodynamic effect on AChR-autoantibody reduction as **VYVGART**, which established the efficacy of **VYVGART Hytrulo**
- The most common ARs observed for **VYVGART** vs placebo were respiratory tract infection (33% vs 29%), headache (32% vs 29%), urinary tract infection (10% vs 5%), paraesthesia (7% vs 5%), and myalgia (6% vs 1%)‡
- Additional common ARs with **VYVGART Hytrulo** are injection site reactions (38%)
- The majority of infections and hematologic abnormalities were mild to moderate in severity
- In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with **VYVGART Hytrulo** or **VYVGART**. Urticaria was also observed in patients treated with **VYVGART Hytrulo**. Please see the Safety section for more information, including postmarketing experience

DELIVERED BY IV OR SC

Two routes to effective symptom control and demonstrated safety: IV infusion with **VYVGART** and subcutaneous injection for HCP administration§ with **VYVGART Hytrulo**.

*Patients were treated with VYVGART + current treatment or placebo + current treatment.
†MG-ADL response was defined as a ≥2-point reduction in the total MG-ADL score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion or injection of the cycle.
‡ARs in ≥5% of patients treated with VYVGART and more frequently than placebo. Headache includes migraine and procedural headache. Paraesthesia includes oral hypoesthesia, hypoesthesia, and hyperesthesia.
§No dilution required. Allow for appropriate storage, preparation, and setup time before use.
AChR=acetylcholine receptor; AR=adverse reaction; gMG=generalized myasthenia gravis; HCP=healthcare professional; IV=intravenous; MG-ADL=Myasthenia Gravis Activities of Daily Living; QMG=Quantitative Myasthenia Gravis; SC=subcutaneous.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS (cont'd)

VYVGART HYTRULO is also contraindicated in patients with serious hypersensitivity to hyaluronidase. Reactions have included anaphylaxis and hypotension leading to syncope.

Please see additional Important Safety Information throughout, full Prescribing Information for VYVGART, and full Prescribing Information for VYVGART Hytrulo.

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