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

VYVGART Hytrulo Overview Brochure

Expand the reach of VYVGART to more patients with **VYVGART Hytrulo**

The first and only IgG Fc-antibody fragment for the treatment of anti-AChR antibody positive gMG is available as VYVGART Hytrulo for subcutaneous injection.[1,3]

With VYVGART Hytrulo, you have a route to effective symptom control and demonstrated safety for your adult patients who prefer subcutaneous administration.[1]

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

Patient portrayal

INDICATION

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infection

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).

Please see additional Important Safety Information throughout and full Prescribing Information.

VYVGART: the first and only IgG Fc-antibody fragment for the treatment of gMG in adult patients who are anti-AChR antibody positive[2,3]

Efgartigimod alfa is the Fc portion of an IgG antibody*—engineered for affinity to FcRn[2,4]

VYVGART Hytrulo is a coformulation of efgartigimod alfa and hyaluronidase. By depolymerizing hyaluronan, hyaluronidase increases permeability of the subcutaneous tissue.[1]

Scan the QR code to learn more about how VYVGART works in blocking FcRn, reducing IgG, and restoring function—a unique approach in the treatment of anti-AChR antibody positive gMG.

*Human IgG-derived.
AChR=acetylcholine receptor; Fab=fragment, antigen-binding; Fc=fragment, crystallized; FcRn=neonatal Fc receptor; gMG=generalized myasthenia gravis; IgG=immunoglobulin G.

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). The majority of infections and hematologic abnormalities were mild to moderate in severity. Delay VYVGART HYTRULO administration 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 VYVGART HYTRULO until the infection has resolved.

How does **VYVGART Hytrulo** work?

VYVGART Hytrulo is a coformulation of efgartigimod alfa (the same active ingredient in VYVGART) and hyaluronidase[1,2]

Not actual size.

Efgartigimod alfa is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG.[1]

Hyaluronidase increases permeability of the subcutaneous tissue by depolymerizing hyaluronan. This effect is transient, and permeability of the subcutaneous tissue is restored within 24 to 48 hours.[1]

IMPORTANT SAFETY INFORMATION (cont'd)

Immunization

Immunization with vaccines during VYVGART HYTRULO treatment has not been studied; the safety with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown.

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The ADAPT trial established the effectiveness of **VYVGART® (efgartigimod alfa-fcab)** for IV infusion in the treatment of gMG in adults who are anti-AChR antibody positive[2]

The ADAPT-SC trial established that VYVGART Hytrulo and VYVGART showed a similar pharmacodynamic (PD) effect in reduction of AChR-Ab levels in adult patients with gMG who are anti-AChR antibody positive, which established the efficacy of VYVGART Hytrulo.[1]

AChR=acetylcholine receptor; AChR-Ab=acetylcholine receptor antibody; gMG=generalized myasthenia gravis; IV=intravenous.

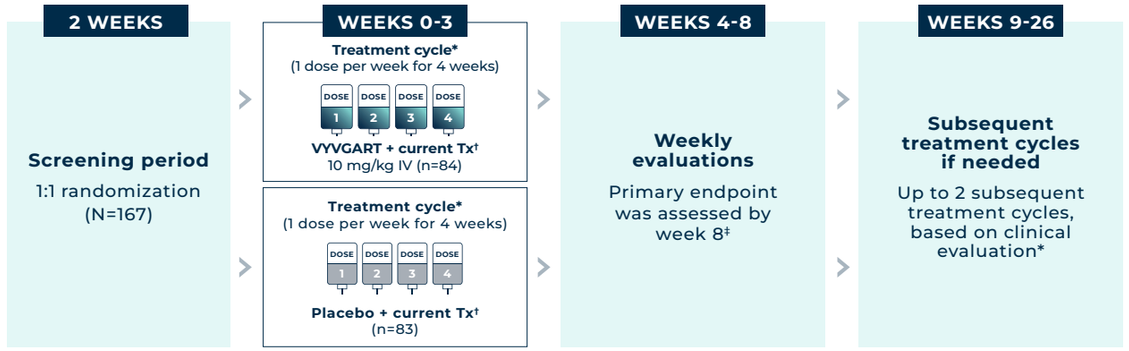
IMPORTANT SAFETY INFORMATION (cont'd)

Immunization (cont'd)

Because VYVGART HYTRULO causes a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during VYVGART HYTRULO treatment. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART HYTRULO.

The ADAPT phase 3 clinical trial studied **VYVGART® (efgartigimod alfa-fcab)** for IV infusion[2,4]

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.
‡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.
MG-ADL=Myasthenia Gravis Activities for Daily Living.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions

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

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The pivotal trial population represented a range of adult patients with gMG[2,4,5]

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; gMG=generalized myasthenia gravis; IV=intravenous; 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.

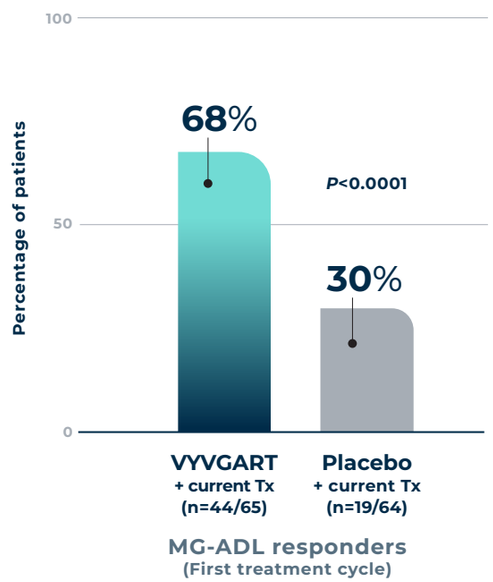
IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions (cont'd)

Monitor patients for at least 30 minutes after administration for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs, institute appropriate supportive measures if needed.

IMPROVEMENT IN DAILY FUNCTION

VYVGART® (efgartigimod alfa-fcab) for IV infusion improved daily function in significantly more patients vs placebo[2,4,6]



AChR=acetylcholine receptor; Tx=treatment.

PRIMARY ENDPOINT

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.

The MG-ADL scale assesses the impact of gMG on daily functions of 8 signs or symptoms that are typically affected in gMG. Each item is assessed on a 4-point scale where a score of 0 represents normal function and a score of 3 represents loss of ability to perform that function. A total score ranges from 0 to 24, with the higher scores indicating more impairment.

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.

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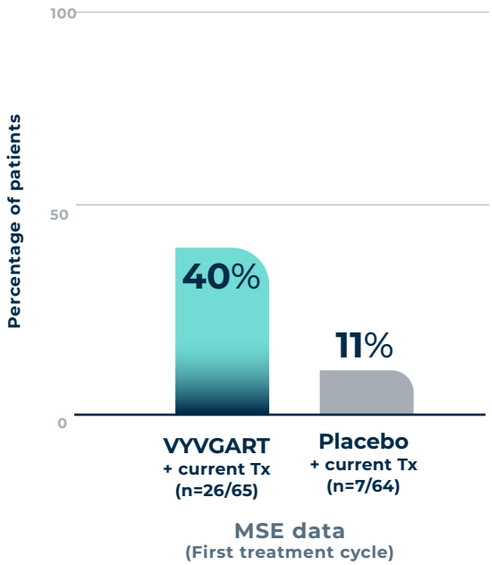
REDUCTION IN MUSCLE WEAKNESS

VYVGART® (efgartigimod alfa-fcab) for IV infusion reduced muscle weakness in significantly more patients vs placebo[2,4,6]

Exploratory endpoint: MG-ADL data for Minimal Symptom Expression (MSE)[2,4,5*]

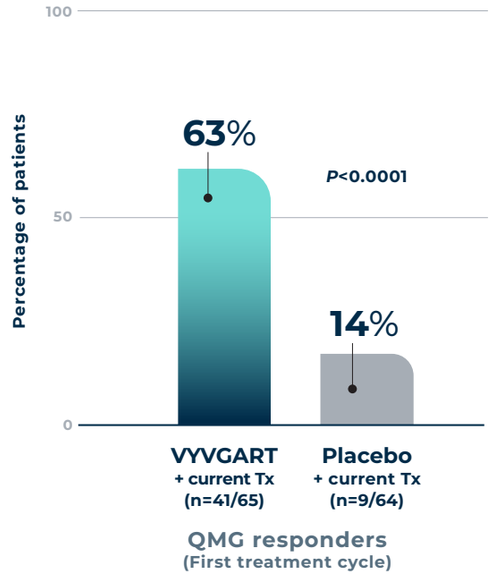
EXPLORATORY ENDPOINT



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: Percentage of anti-AChR antibody positive patients with MSE 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.
†MSE evaluation occurred at any visit from week 1 through week 26.
AChR=acetylcholine receptor; MG-ADL=Myasthenia Gravis Activities of Daily Living; Tx=treatment.



QMG=Quantitative Myasthenia Gravis.

SECONDARY ENDPOINT

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.

The QMG total score is a 13-item categorical grading system that assesses muscle weakness. Each item is assessed on a 4-point scale where a score of 0 represents no weakness and a score of 3 represents severe weakness. A total possible score ranges from 0 to 39, where higher scores indicate more severe impairment.

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. 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.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd)

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.

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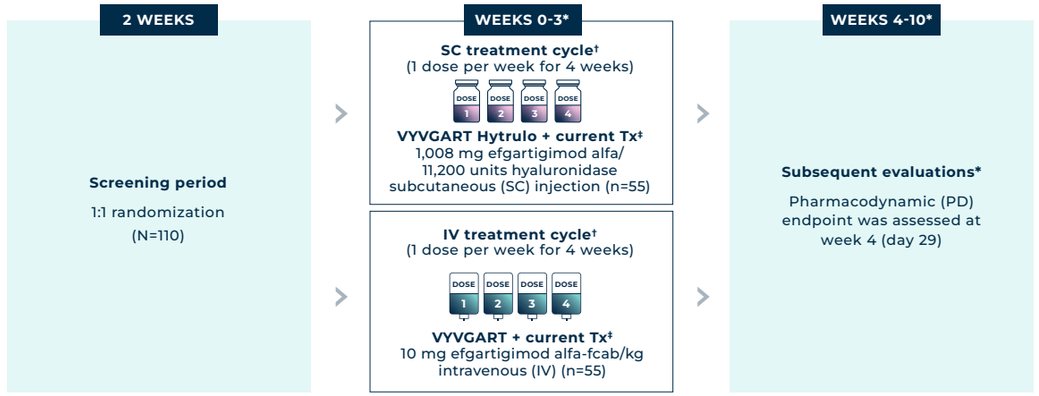
The ADAPT-SC phase 3 study evaluated **VYVGART Hytrulo** for subcutaneous injection[1,5,7,8]

A 10-week, phase 3, multicenter, randomized, open-label, parallel-group trial in 110 adults 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.
AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; MG-ADL=Myasthenia Gravis Activities of Daily Living; Tx=treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

USE IN SPECIFIC POPULATIONS

Pregnancy

As VYVGART HYTRULO is 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 HYTRULO in utero.

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)

Acetylcholinesterase 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.
MGFA=Myasthenia Gravis Foundation of America; NSIST=nonsteroidal immunosuppressive therapy; QMG=Quantitative Myasthenia Gravis.

IMPORTANT SAFETY INFORMATION (cont'd)

Lactation

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

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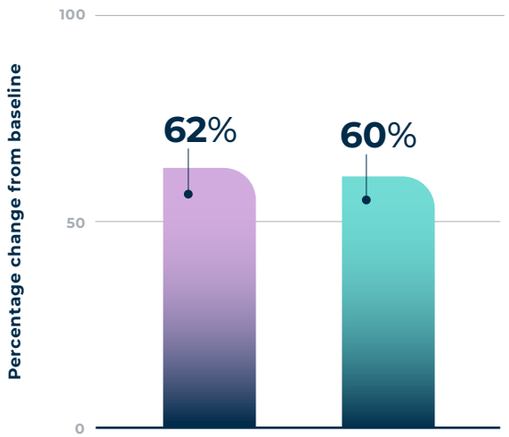
VYVGART Hytrulo and **VYVGART®** **(efgartigimod alfa-fcab):** similar pharmacodynamic (PD) effect in reduction of AChR-Ab levels at week 4[1,2,5*†]



PD ENDPOINT

PD effect of VYVGART Hytrulo for SC injection and VYVGART for IV infusion 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.

A post-hoc analysis observed noninferiority (NI) between VYVGART Hytrulo and VYVGART in the reduction of AChR-Ab levels at week 4.

The NI evaluation was based on the percent reduction from baseline in AChR-Ab levels at day 29 (ie, week 4), using an NI margin of 10%.

The least squares mean difference in the percent change from baseline of AChR-Ab levels was 2.5% (95% CI: -7.45 to 2.41), which is below the upper limit of the CI of 10%.

POST-HOC ANALYSIS

Study Limitations: ADAPT-SC was a bridging study designed to compare pharmacodynamic effects between VYVGART Hytrulo for subcutaneous injection and VYVGART for intravenous infusion. Noninferiority of AChR-Ab reduction was observed as a post-hoc analysis; therefore, data should be interpreted with caution and conclusions cannot be drawn

*The 90% confidence interval for the geometric mean ratios of AChR-Ab reduction at day 29 and $AEC_{0\text{-}4w}$ (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=acetylcholine receptor; AChR-Ab=acetylcholine receptor antibody; IgG=immunoglobulin G; IV=intravenous; SC=subcutaneous; Tx=treatment.

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 HYTRULO and any potential adverse effects on the breastfed infant from VYVGART HYTRULO or from the underlying maternal condition.

IMPORTANT SAFETY INFORMATION (cont'd)

Please see the full Prescribing Information.

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).

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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® (efgartigimod alfa-fcab)**[1,2,9]

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

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

IV=intravenous.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infection

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).

In ADAPT-SC, injection site reactions occurred in 38% of patients receiving VYVGART Hytrulo for SC injection. 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)‡

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. In clinical trials, hypersensitivity reactions were mild or moderate, occurred within one hour to three weeks of administration, and did not lead to treatment discontinuation.

‡Interim results presented April 2023. The ADAPT-SC Open Label Extension study is still ongoing.
SC=subcutaneous.

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). The majority of infections and hematologic abnormalities were mild to moderate in severity. Delay VYVGART HYTRULO administration 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 VYVGART HYTRULO until the infection has resolved.

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VYVGART Hytrulo: ongoing treatment with an individualized dosing schedule based on clinical evaluation of patient needs[1,2]

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

1 TREATMENT CYCLE = 1 INJECTION PER WEEK FOR 4 WEEKS

(1,008 mg efgartigimod alfa/11,200 units hyaluronidase)
~30-90–second injection*

SUBSEQUENT TREATMENT CYCLES

Administer subsequent treatment cycles based on clinical evaluation

The safety of initiating subsequent cycles sooner than 4 weeks from the last injection of the previous treatment cycle has not been established.

It may help to schedule subsequent cycles in advance.

You may find it helpful for your patients to track their gMG symptoms and any adverse reactions during treatment to assist you with determining their next treatment cycle.

*Refers to actual injection time of VYVGART Hytrulo. Allow for appropriate storage, preparation, and setup time before use. gMG=generalized myasthenia gravis.

IMPORTANT SAFETY INFORMATION (cont'd)

Immunization

Immunization with vaccines during VYVGART HYTRULO treatment has not been studied; the safety with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown.

Help your patients save on their treatment with **VYVGART Hytrulo**

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

- If you have enrolled your commercially insured patient in **My VYVGART® Path**, a Nurse Case Manager can enroll them in the **VYVGART Co-pay Program** and answer their questions
- If your patient does not have commercial or private insurance, a Nurse Case Manager can help them understand potential financial assistance programs

GET DIRECT SUPPORT FOR YOUR PRACTICE

Field Reimbursement Managers are available to educate your practice about acquiring VYVGART Hytrulo, including **insurance approvals**, **reimbursement**, and **co-pay assistance**.

†Eligible commercially insured patients may pay as little as $0 for 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 (cont'd)

Immunization (cont'd)

Because VYVGART HYTRULO causes a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during VYVGART HYTRULO treatment. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART HYTRULO.

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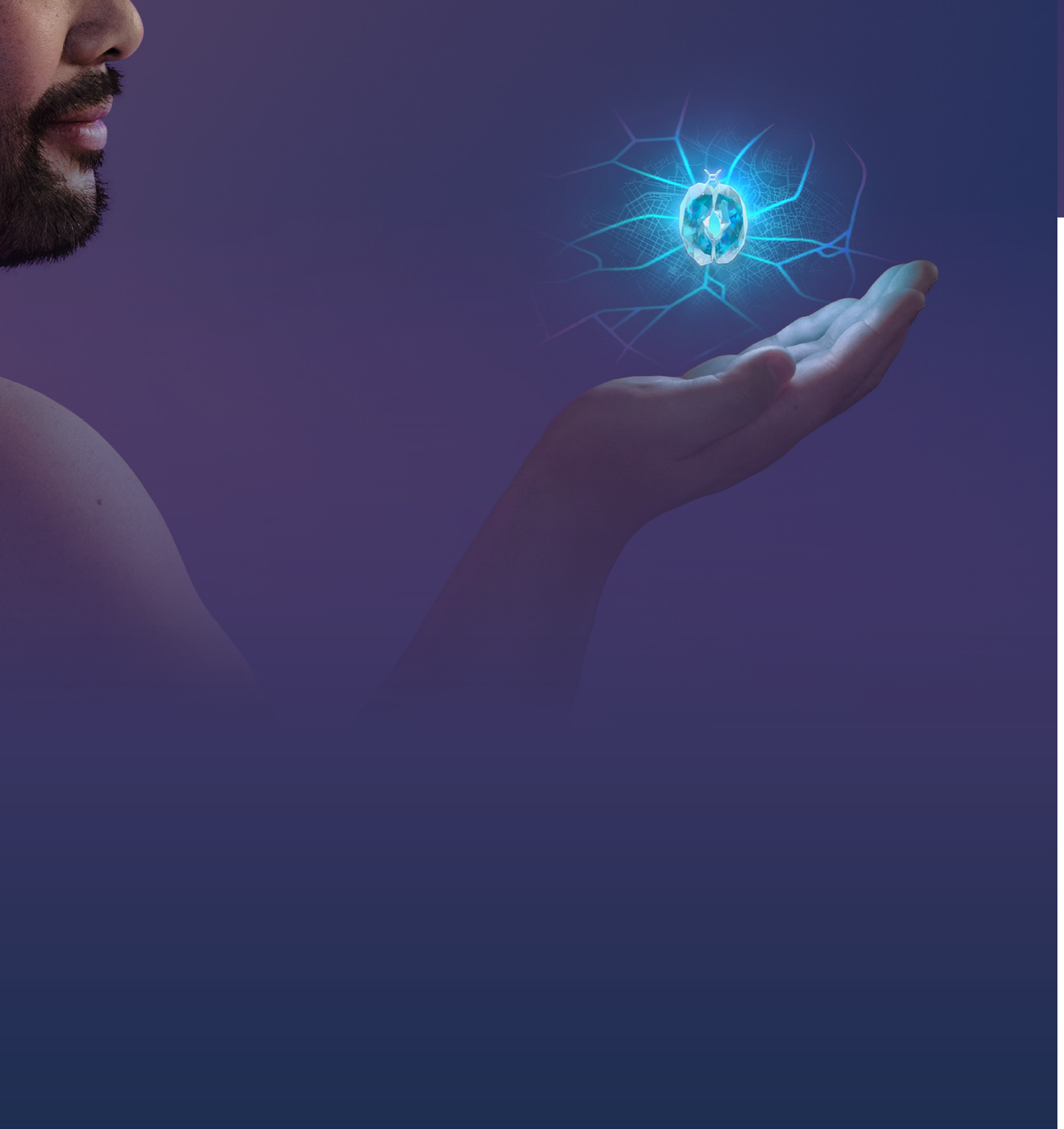
Subcutaneous Injection
180 mg/mL and 2000 U/mL vial



Patient portrayal

Get personalized support with My VYVGART® Path

The committed team at My VYVGART Path—our comprehensive patient support program—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

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

Representative portrayal

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions

Hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART HYTRULO and efgartigimod alfa-fcab. Urticaria was also observed in patients treated with VYVGART HYTRULO. In clinical trials, hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation. Monitor patients for at least 30 minutes after administration for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs, institute appropriate supportive measures if needed.

Please see additional Important Safety Information throughout and full Prescribing Information.

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

Patient portrayal

Enroll your patients today and get them started

Two ways to enroll patients in My VYVGART® Path

Online Enrollment

Scan the QR code or visit VYVGARTHCP.com/enroll to fill out and submit the enrollment form

Enrollment via Fax

Download the enrollment form and fax the completed document to 1-833-698-7284

References: 1. VYVGART Hytrulo. Prescribing information. argenx US Inc; 2023. **2.** VYVGART. Prescribing information. argenx US Inc; 2022. **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.** Data on file, argenx US Inc. June 2023. **6.** Wolfe GI et al. *Neurology*. 1999;52(7):1487-1489. doi:10.1212/wnl.52.7.1487 **7.** Casey J et al. Poster presented at: 27th International Hybrid Annual Congress of the World Muscle Society; October 2022; Halifax, Nova Scotia, Canada. **8.** ClinicalTrials.gov. NCT04735432. Accessed June 20, 2023. https://classic.clinicaltrials.gov/ct2/show/NCT04735432 **9.** Casey J et al. Poster presented at: American Academy of Neurology (AAN) Annual Meeting; April 22-27, 2023; Boston, MA.

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.

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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infection

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 VYVGART HYTRULO administration 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 VYVGART HYTRULO until the infection has resolved.

Immunization

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

Hypersensitivity Reactions

Hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART HYTRULO and efgartigimod alfa-fcab. Urticaria was also observed in patients treated with VYVGART HYTRULO. In clinical trials, hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation. Monitor patients for at least 30 minutes after administration for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs, institute appropriate supportive measures if needed.

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 HYTRULO is 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 HYTRULO in utero.

Lactation

There is no information regarding the presence of 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 HYTRULO and any potential adverse effects on the breastfed infant from VYVGART HYTRULO or from the underlying maternal condition.

Please see the full Prescribing Information.

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).

Please see additional Important Safety Information throughout and full Prescribing Information.

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

Efficacy and safety with another route of administration for adult patients with anti-AChR antibody positive gMG[1,2]

DEMONSTRATED EFFICACY AND SAFETY

- **VYVGART® (efgartigimod alfa-fcab)** for IV infusion improved daily function (MG-ADL) and reduced muscle weakness (QMG) in significantly more patients vs placebo*†‡
- **VYVGART Hytrulo** demonstrated a similar pharmacodynamic effect on AChR antibody 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 adverse reactions with **VYVGART Hytrulo** are injection site reactions

DELIVERED BY SC

VYVGART Hytrulo is a ready-to-use solution for injection‖

Personalized support is available for you and your patients with

My VYVGART® Path

Learn more about VYVGART Hytrulo at VYVGARTHCP.com

*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.
‡QMG response was 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.
§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

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. 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.

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