



Patient portrayals

Explore clinical data from ADAPT and ADAPT-SC

In adults with anti-AChR antibody positive gMG^{1,2}

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

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

AChR=acetylcholine receptor; gMG=generalized myasthenia gravis.

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

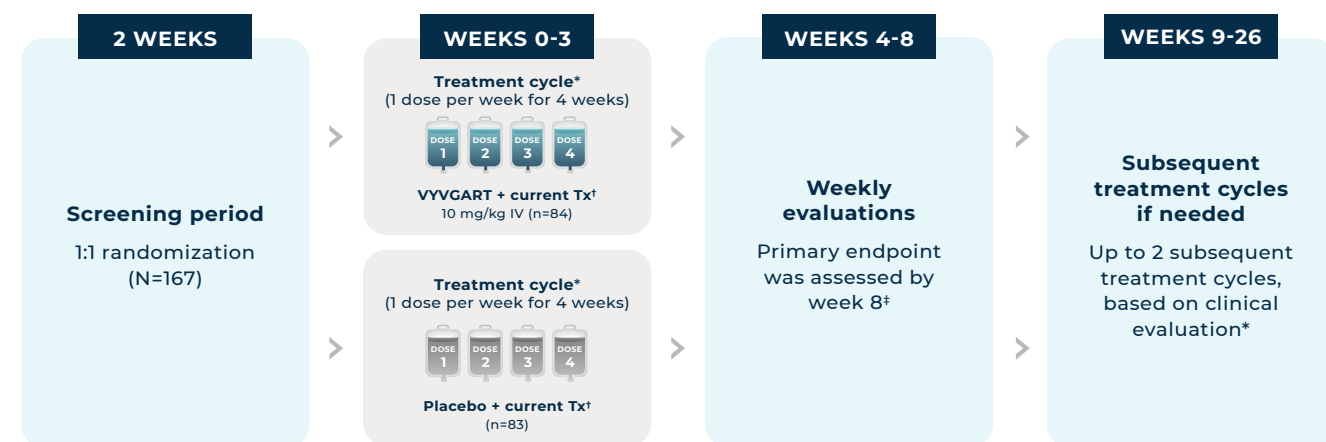
CONTRAINDICATIONS

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 and full [Prescribing Information](#) for VYVGART Hytrulo and full [Prescribing Information](#) for VYVGART.

The ADAPT phase 3 clinical trial^{1,3}

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)

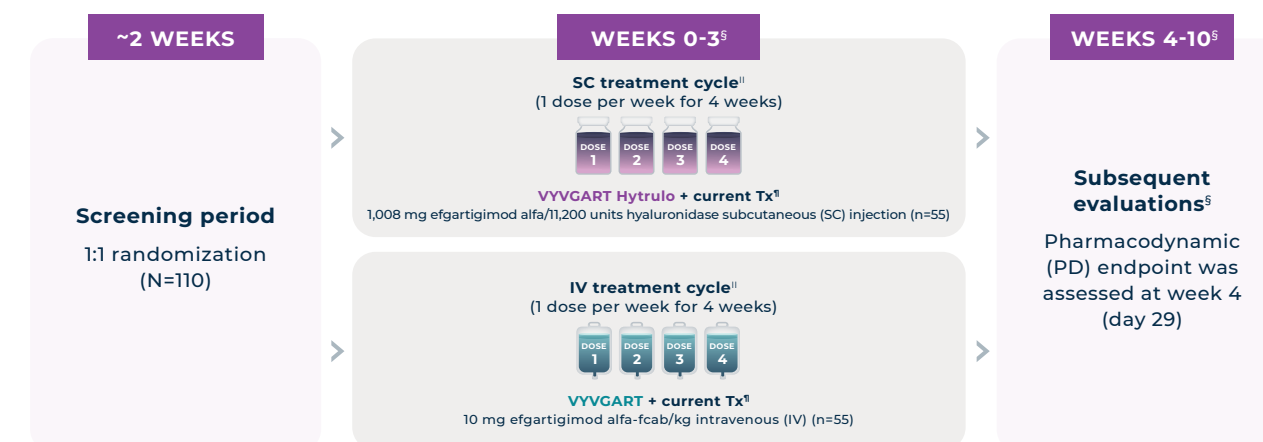
WARNINGS AND PRECAUTIONS

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). 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.

The ADAPT-SC phase 3 clinical trial^{2,4,5}

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)

Immunization

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

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

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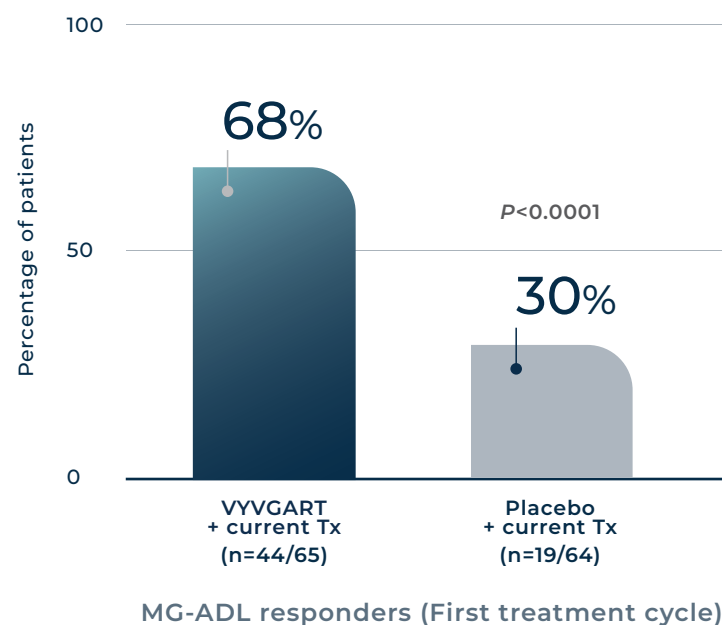
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>2x as many patients had improvement in daily function sustained for ≥4 weeks during the first treatment cycle^{1,3*}

>4x as many patients had reduction in muscle weakness sustained for ≥4 weeks during the first treatment cycle^{1,3*}

PRIMARY ENDPOINT

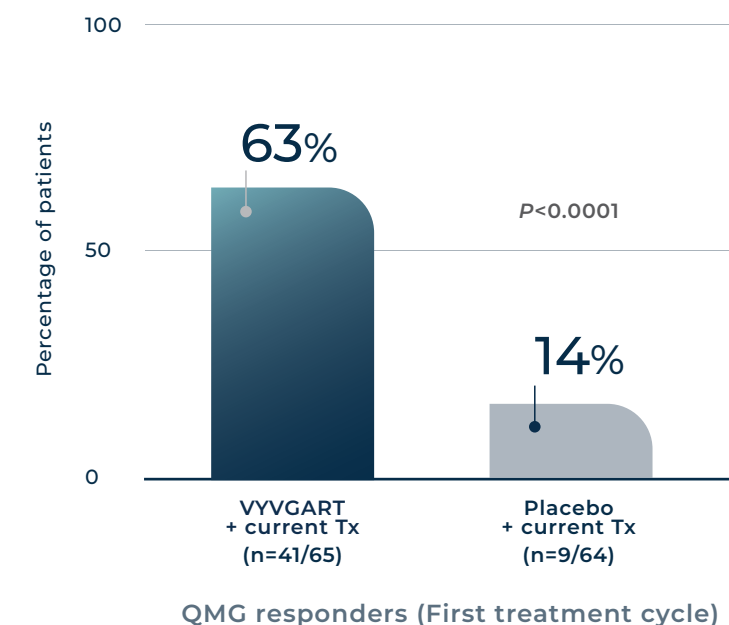
≥2 POINT REDUCTION in MG-ADL score from baseline for at least 4 consecutive weeks during the first treatment cycle



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.¹

SECONDARY ENDPOINT

≥3 POINT REDUCTION in QMG score from baseline for at least 4 consecutive weeks during the 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.

*Data from the ADAPT clinical trial.
AChR=acetylcholine receptor; MG-ADL=Myasthenia Gravis Activities of Daily Living; Tx=treatment.

QMG=Quantitative Myasthenia Gravis.

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. 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.

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.

Please see additional Important Safety Information throughout and full [Prescribing Information for VYVGART Hytrulo](#) and full [Prescribing Information for VYVGART](#).

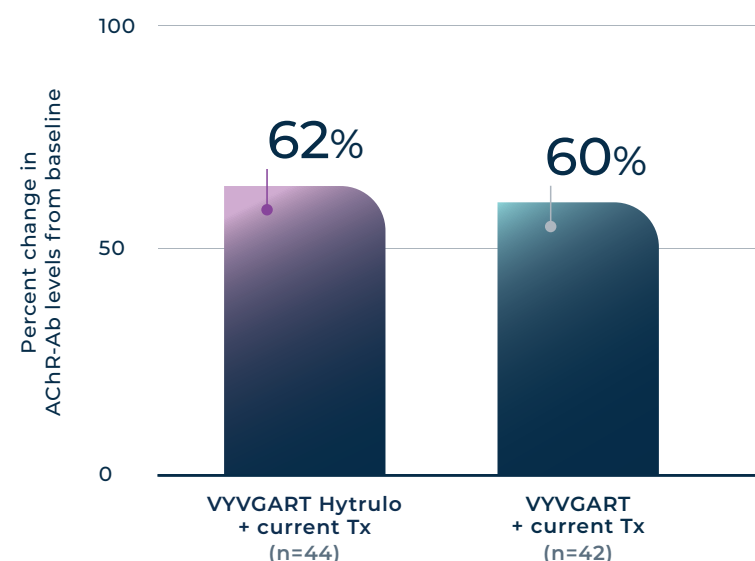
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Comparable pharmacodynamic effect for **VYVGART Hytrulo**^{2,6*†‡}

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.

*Data from the ADAPT-SC clinical trial.

†The 90% confidence interval for the geometric mean ratios of AChR-Ab reduction at day 29 and AUEC_{0-4w} (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; PD=pharmacodynamic; SC=subcutaneous; Tx=treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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Exploratory endpoint: MG-ADL data for Minimal Symptom Expression (MSE)^{1,3,7,8*†}

Post-hoc analysis: MG-ADL data for MSE for **VYVGART Hytrulo** and **VYVGART**^{8-10§||}

EXPLORATORY ENDPOINT

Observed during at least one visit in the first treatment cycle:



Percentage of patients with observed 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[‡]

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.

POST-HOC ANALYSIS

Observed during at least one visit during the study:



Percentage of patients with observed 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 study^{||}

Limitations: ADAPT-SC was a bridging study designed to compare pharmacodynamic effects between **VYVGART Hytrulo** for subcutaneous injection and **VYVGART** for intravenous infusion. MSE was observed post hoc; therefore, data should be interpreted with caution and conclusions cannot be drawn.

*Data from the ADAPT clinical trial.

[†]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.

[§]Data from the ADAPT-SC clinical trial.

^{||}Clinical trial data from patients who were anti-AChR antibody positive.

[¶]MSE evaluation occurred at any visit from week 1 through week 10.

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. Risk and benefits should be considered prior to administering live vaccines to infants exposed to VYVGART or VYVGART HYTRULO in utero.

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Demonstrated safety profile in the ADAPT clinical trial¹

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)

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. Maternal IgG is known to be present in human milk. 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.

A consistent safety profile in the ADAPT-SC clinical trial^{1,2,11}

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 the ADAPT clinical trial, the most common adverse reactions for VYVGART-treated patients were respiratory tract infection, headache, and urinary tract infection.

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)

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).

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INDICATION AND IMPORTANT SAFETY INFORMATION

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INDICATION

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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

Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART or VYVGART HYTRULO. The safety of immunization with live vaccines and the immune response to vaccination during treatment with VYVGART or VYVGART HYTRULO are unknown. Because VYVGART and VYVGART HYTRULO cause a reduction in immunoglobulin G (IgG) levels, vaccination with live vaccines is not recommended during treatment 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 ($\geq 10\%$) adverse reactions in efgartigimod alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. In Study 2, the most common ($\geq 10\%$) 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. Risk and benefits should be considered prior to administering live vaccines to infants exposed to VYVGART or VYVGART HYTRULO in utero.

Lactation

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References: **1.** VYVGART. Prescribing information. argenx US Inc; 2024. **2.** VYVGART Hytrulo. Prescribing information. argenx US Inc; 2024. **3.** Howard JF Jr et al. *Lancet Neurol.* 2021;20(7):526-536. doi:10.1016/S1474-4422(21)00159-9 **4.** Howard JF Jr et al. *Neurotherapeutics.* 2024;21(5):1-12. doi:10.1016/j.neurot.2024.e00378 **5.** ClinicalTrials.gov. NCT04735432. Accessed October 17, 2024. <https://clinicaltrials.gov/ct2/show/NCT04735432> **6.** Data on file. REF-01900. argenx US Inc. June 2023. **7.** Data on file. REF-00724. argenx US Inc. December 2021. **8.** Uzawa A et al. *Acta Neurol Belg.* 2023;123(3):979-982. doi:10.1007/s13760-022-02162-1 **9.** Data on file. REF-01895. argenx US Inc. June 2023. **10.** Wolfe GI et al. *Neurology.* 1999;52(7):1487-1489. doi:10.1212/wnl.52.7.1487 **11.** Howard JF Jr et al. Poster presented at: American Academy of Neurology (AAN) Annual Meeting; April 22-27, 2023. Boston, MA.



Learn more about **VYVGART Hytrulo**
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