Patient portrayal

EXPLORE CLINICAL DATA

Explore clinical data from ADAPT

In adult patients with anti-AChR antibody positive gMG[1]

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) is indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

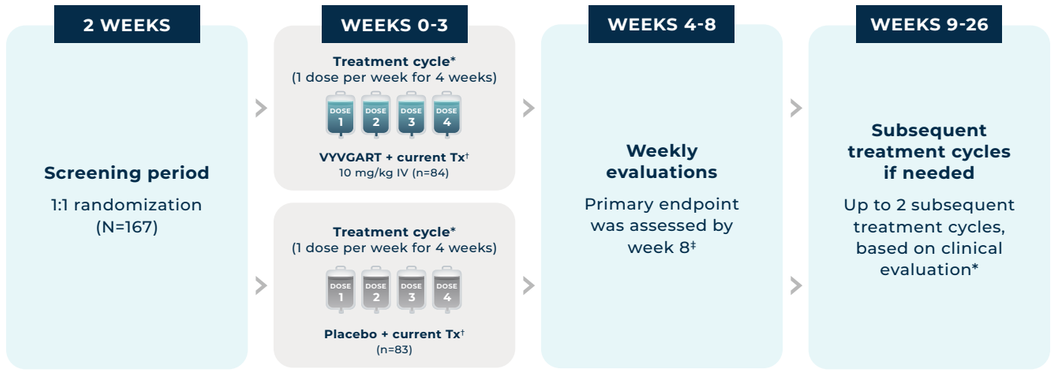
VYVGART is contraindicated in patients with serious hypersensitivity to efgartigimod alfa products or to any of the excipients of VYVGART. Reactions have included anaphylaxis and hypotension leading to syncope.

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

The ADAPT phase 3 clinical trial[1,2]

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

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.

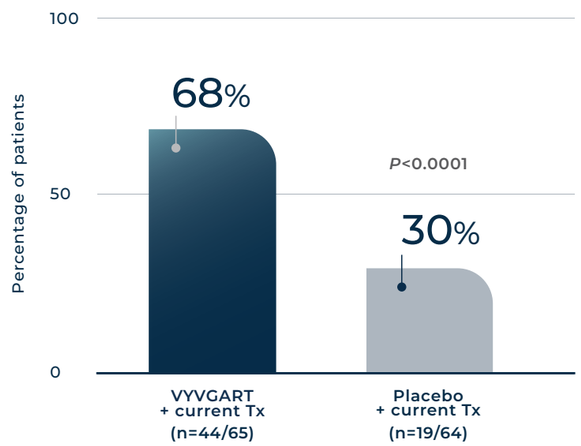
†All patients received stable doses of their current gMG treatment.

‡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.

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.[1]

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Infection

VYVGART may increase the risk of infection. The most common infections observed in Study 1 were urinary tract infection (10% for VYVGART vs 5% for placebo) and respiratory tract infections (33% for VYVGART vs 29% for placebo). Patients on VYVGART 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 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 until the infection has resolved.

IMPORTANT SAFETY INFORMATION (cont'd)

Immunization

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

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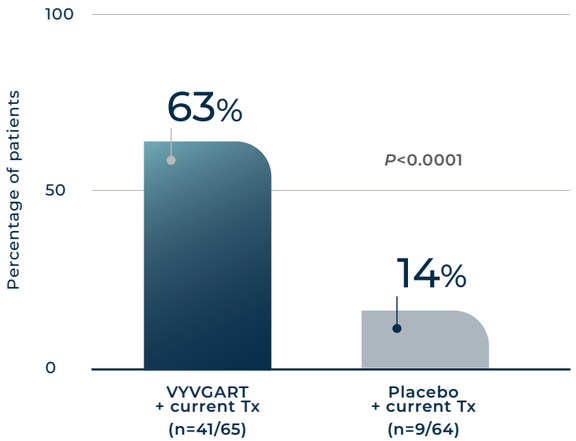
>4x as many patients had reduction in muscle weakness sustained for ≥4 weeks during the first treatment cycle[1,2]

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.

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

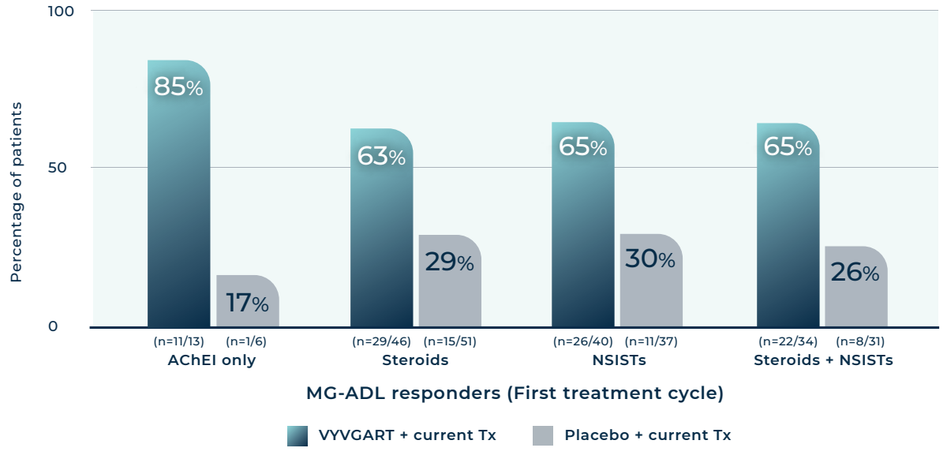
IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in VYVGART-treated patients. 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 VYVGART. Anaphylaxis and hypotension occurred during or within an hour of administration and led to infusion discontinuation and in some cases to permanent treatment discontinuation. Monitor patients during administration and for 1 hour thereafter 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.

Post-hoc analysis: MG-ADL response data during the first treatment cycle across current therapies[1,3*†]

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.

*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; gMG=generalized myasthenia gravis; MG-ADL=Myasthenia Gravis Activities of Daily Living; NSIST=nonsteroidal immunosuppressive therapy.

IMPORTANT SAFETY INFORMATION (cont'd)

Infusion-Related Reactions

Infusion-related reactions have been reported with VYVGART 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.

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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)

Infusion-Related Reactions (cont'd)

If a severe infusion-related reaction occurs during administration, discontinue VYVGART infusion and initiate appropriate therapy. Consider the risks and benefits of readministering VYVGART 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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INDICATION AND IMPORTANT SAFETY INFORMATION

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Immunization

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Infusion-Related Reactions

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ADVERSE REACTIONS

In Study 1, the most common (≥10%) adverse reactions with VYVGART were respiratory tract infection, headache, and urinary tract infection.

USE IN SPECIFIC POPULATIONS

Pregnancy

As VYVGART 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 in utero.

Lactation

There is no information regarding the presence of efgartigimod alfa-fcab 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 and any potential adverse effects on the breastfed infant from VYVGART 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).

References: 1. VYVGART. Prescribing information. argenx US Inc; 2023. **2.** Howard JF Jr et al. *Lancet Neurol*. 2021;20(7):526-536. doi:10.1016/S1474-4422(21)00159-9 **3.** Karam C et al. Presented at: Myasthenia Gravis Foundation of America (MGFA) National Conference; April 11-13, 2021. Canada. Virtual.

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Learn more about VYVGART clinical trial data at VYVGARTHCP.com

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