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

VYVGART Overview Brochure

The first and only IgG Fc-antibody fragment for the treatment of **generalized myasthenia gravis (gMG)** in adult patients who are anti-acetylcholine receptor (AChR) antibody positive[1,2]

VYVGART: recharging the neuromuscular junction[3,4]

VYVGART binds to and blocks the neonatal Fc receptor (FcRn), resulting in the reduction of immunoglobulin G (IgG) antibodies, including AChR autoantibodies.[1]

Fc=fragment, crystallized.

Patient portrayal

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

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 infection (33% for VYVGART vs 29% for placebo).

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[1,2]

VYVGART is the Fc portion of an IgG antibody*—engineered for affinity to FcRn[1,5]

*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)

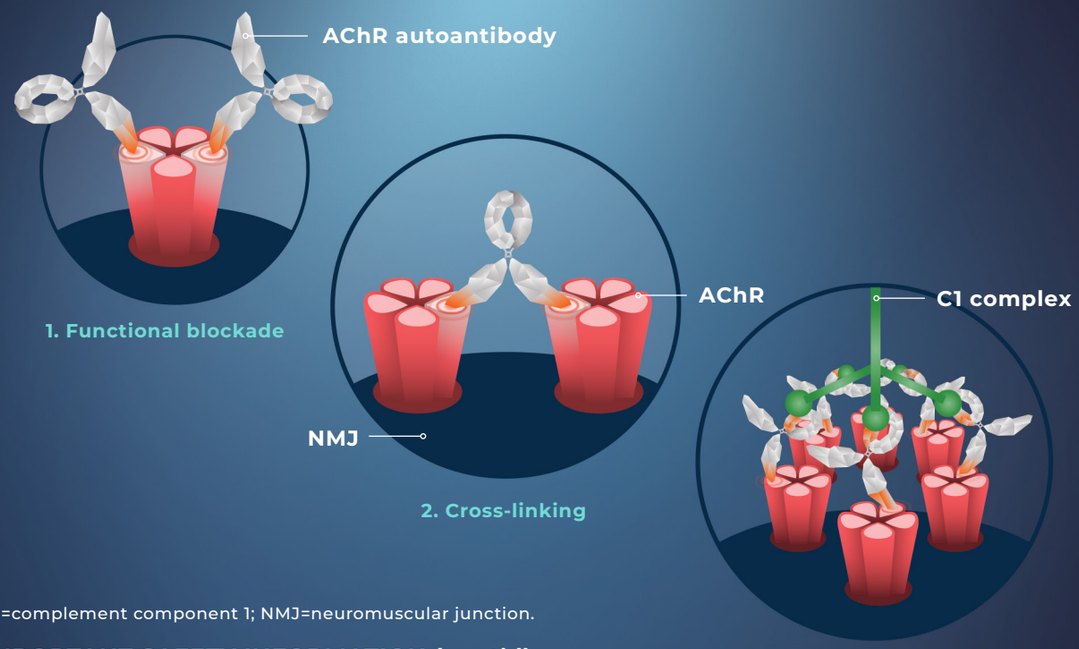
Infection (cont'd)

Patients on 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 is 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.

AChR autoantibodies exert a direct pathogenic effect in gMG[6-10]

AChR autoantibodies disrupt neurotransmission in 3 ways[6-10]:

1. **Binding** to AChR and creating a functional blockade
2. **Cross-linking** of AChR, leading to internalization and degradation
3. **Activating** the autoantibody dependent complement system



C1=complement component 1; NMJ=neuromuscular junction.

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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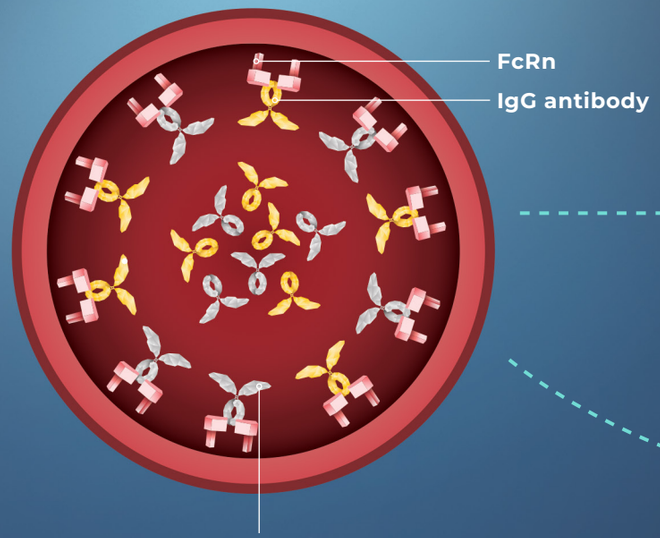
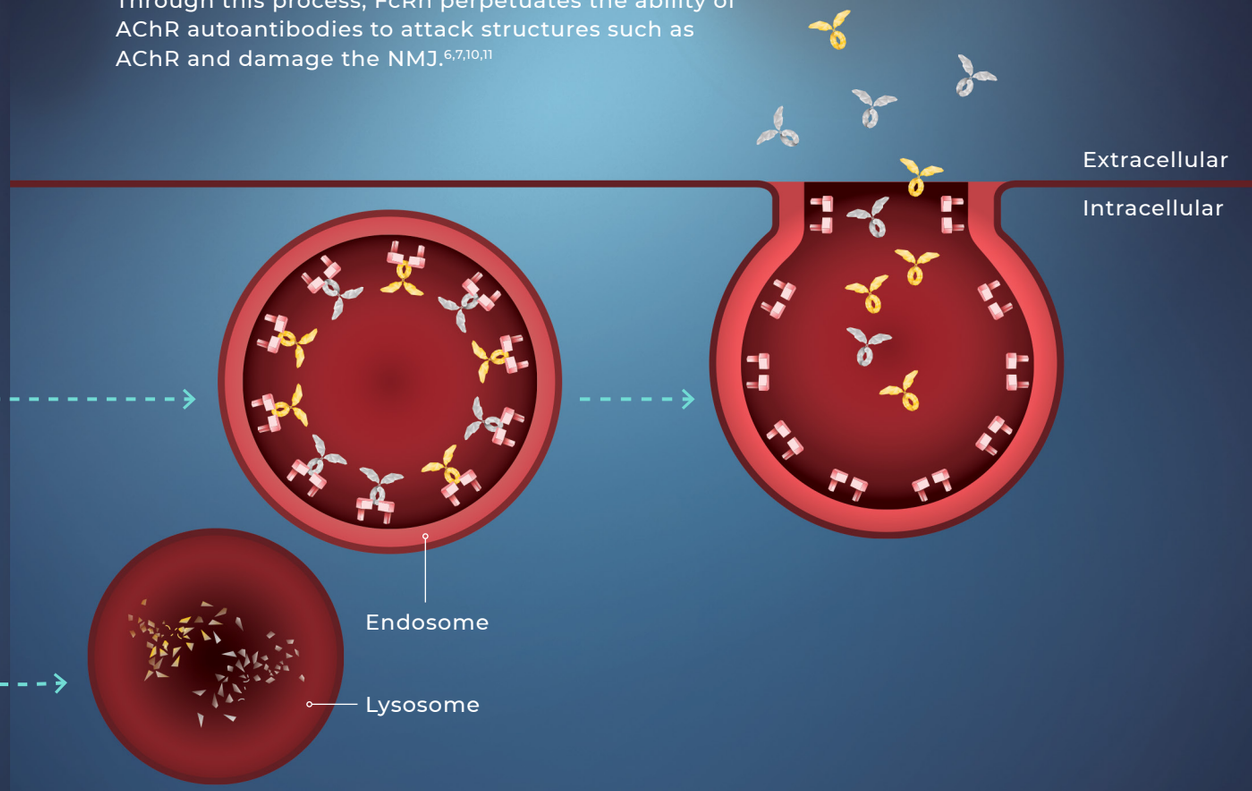
FcRn plays a key role in gMG by perpetuating IgG antibodies[6-10]

FcRn binds IgG antibodies, preventing them from being destroyed in the lysosome. In doing so, FcRn helps maintain high levels of circulating IgG antibodies, including AChR autoantibodies.[6,7,10,11]



Through this process, FcRn perpetuates the ability of AChR autoantibodies to attack structures such as AChR and damage the NMJ.[6,7,10,11]



AChR=acetylcholine receptor; FcRn=neonatal Fc receptor; gMG=generalized myasthenia gravis; IgG=immunoglobulin G; NMJ=neuromuscular junction.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions

Hypersensitivity reactions, including rash, angioedema, and dyspnea, were observed with VYVGART.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions (cont'd)

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 during administration and for 1 hour thereafter for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs during administration, discontinue VYVGART infusion and institute appropriate supportive measures if needed.

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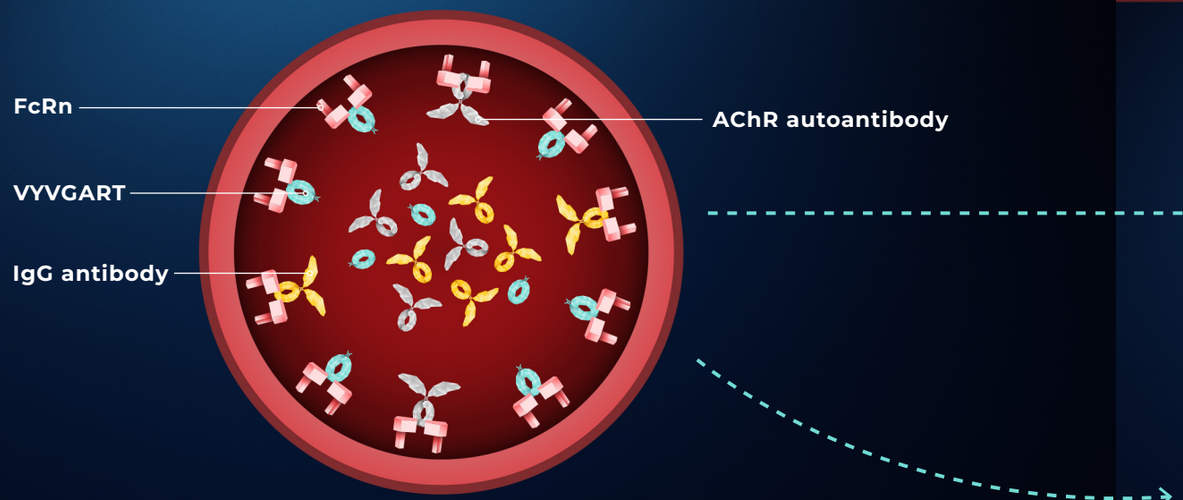
VYVGART targets FcRn, a unique approach in the treatment of anti-AChR antibody positive gMG[1,2]

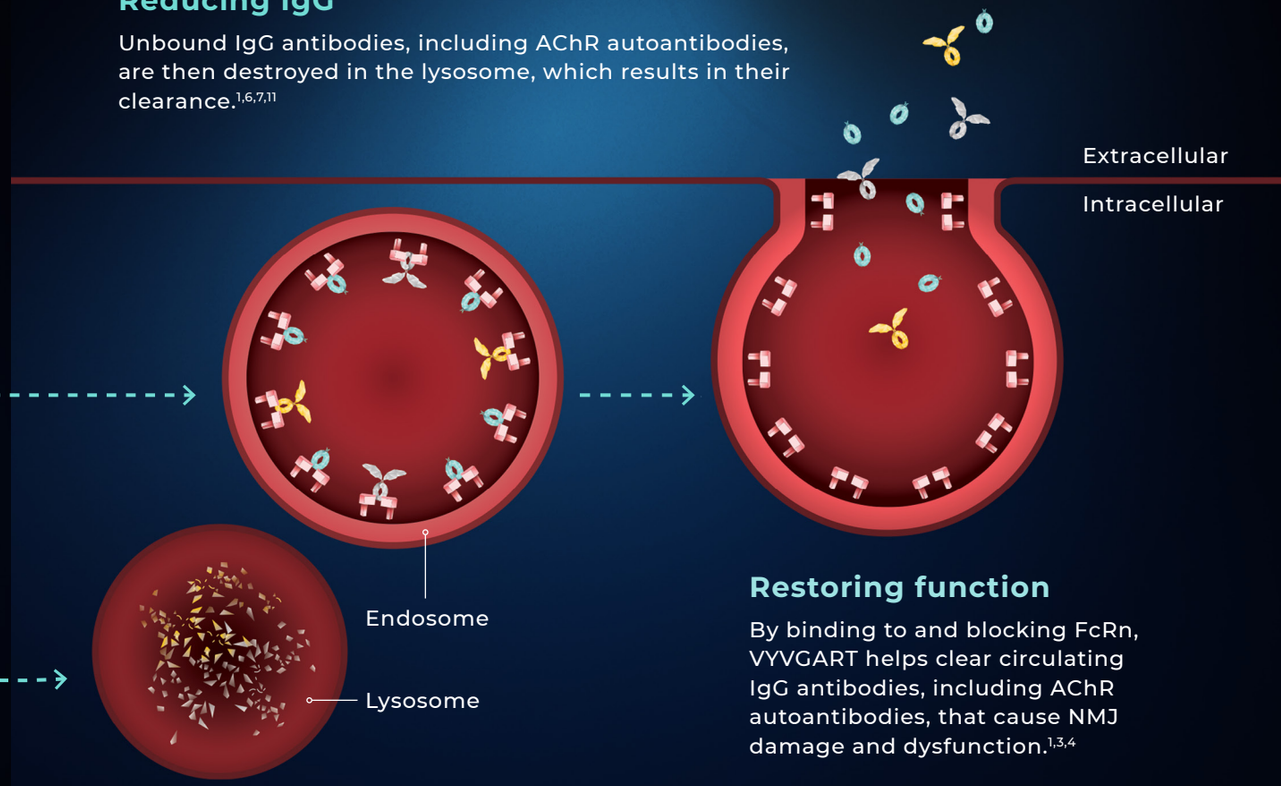
Block FcRn

VYVGART competes with IgG antibodies, including AChR autoantibodies, in binding to and blocking FcRn.[1,5]



Reducing IgG

Unbound IgG antibodies, including AChR autoantibodies, are then destroyed in the lysosome, which results in their clearance.[1,6,7,11]



Restoring function

By binding to and blocking FcRn, VYVGART helps clear circulating IgG antibodies, including AChR autoantibodies, that cause NMJ damage and dysfunction.[1,3,4]

AChR=acetylcholine receptor; FcRn=neonatal Fc receptor; gMG=generalized myasthenia gravis; IgG=immunoglobulin G; NMJ=neuromuscular junction.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

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

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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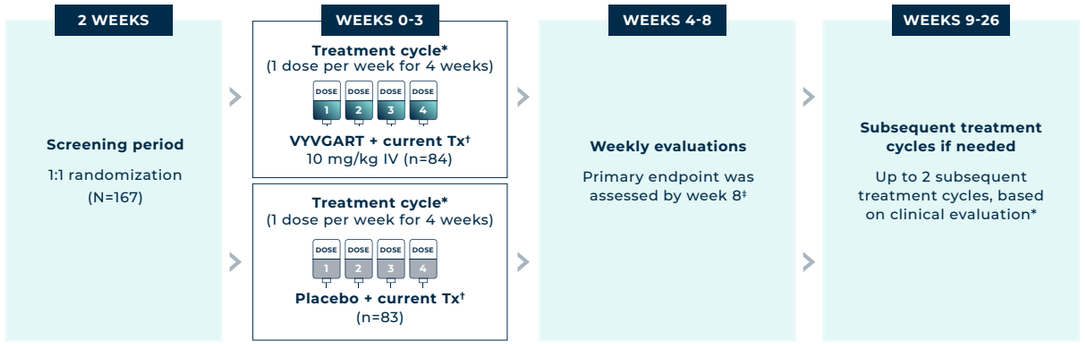
The ADAPT phase 3 clinical trial[1,5]

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

IMPORTANT SAFETY INFORMATION (cont'd)

Lactation

There is no information regarding the presence of VYVGART 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 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).

The pivotal trial population represented a range of adult patients with gMG[1,5,12]

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 percentage 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; 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

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 infection (33% for VYVGART vs 29% for placebo).

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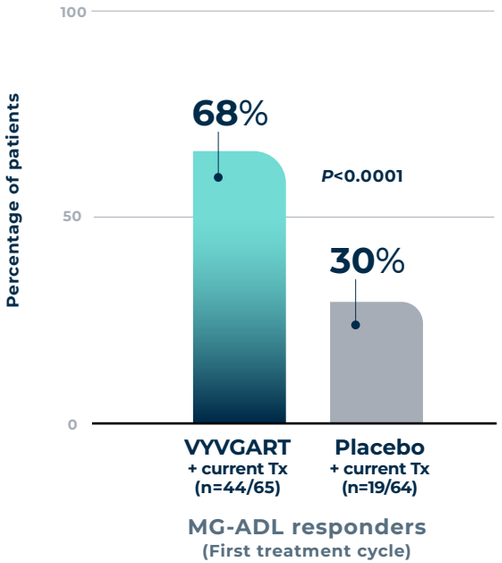
IMPROVEMENT IN DAILY FUNCTION

VYVGART improved daily function in significantly more patients vs placebo[1,5]

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.[1]

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.[1,13]

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

IMPORTANT SAFETY INFORMATION (cont'd)

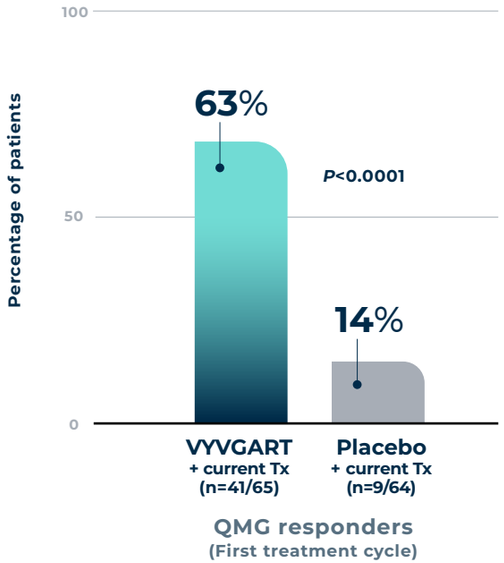
Infection (cont'd)

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 is 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.

REDUCTION IN MUSCLE WEAKNESS

VYVGART reduced muscle weakness in significantly more patients vs placebo[1,5]

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.[1]

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.[1,13]

QMG=Quantitative Myasthenia Gravis.

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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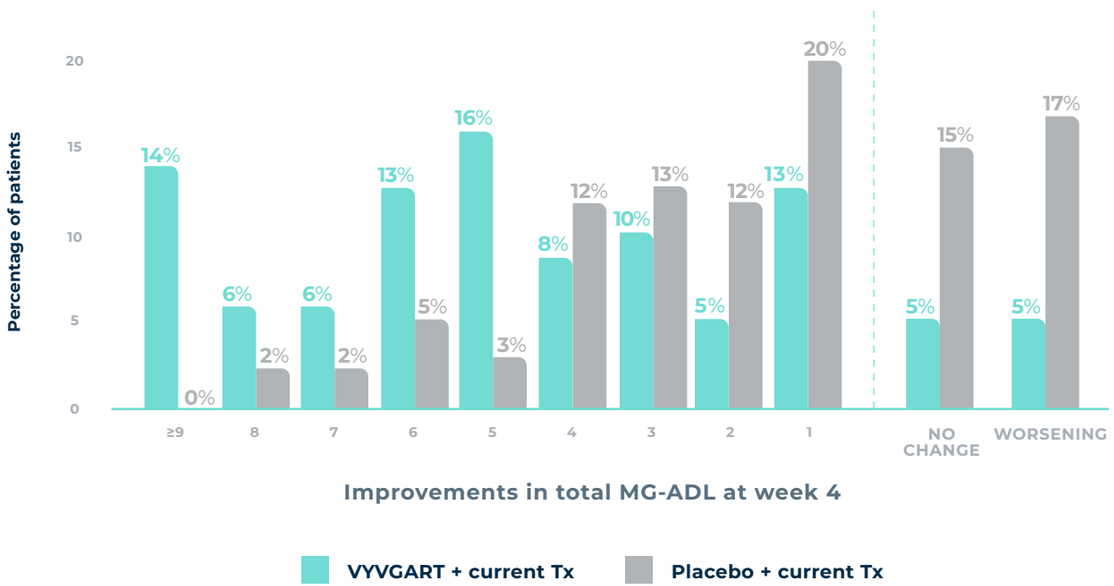
VYVGART demonstrated greater improvement in daily function vs placebo at week 4[1*†]



*Clinical trial data from patients who were anti-AChR antibody positive.
†Four weeks after the initial infusion of the first treatment cycle.
AChR=acetylcholine receptor; MG-ADL=Myasthenia Gravis Activities of Daily Living; Tx=treatment.

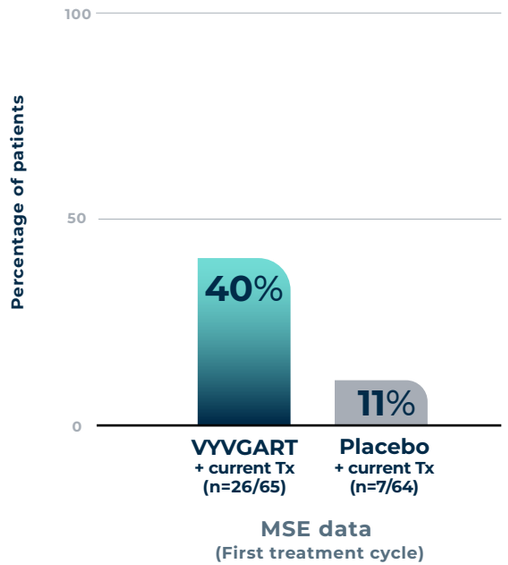
IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions

Hypersensitivity reactions, including rash, angioedema, and dyspnea, were observed with VYVGART. 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.

Exploratory endpoint: MG-ADL data for Minimal Symptom Expression (MSE)[5,12‡]

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.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity Reactions (cont'd)

Monitor patients during administration and for 1 hour thereafter for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs during administration, discontinue VYVGART infusion and institute appropriate supportive measures if needed.

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VYVGART had a demonstrated safety profile in the ADAPT clinical trial[1]

Adverse reactions in ≥5% of patients treated with VYVGART 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.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

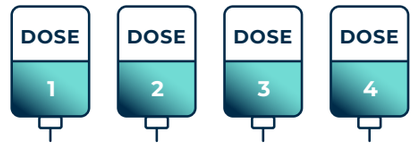
The most common (≥10%) adverse reactions with VYVGART were respiratory tract infection, headache, and urinary tract infection.

VYVGART: an individualized dosing schedule based on clinical evaluation[1]

The recommended dose of VYVGART is 10 mg/kg, given in treatment cycles of once-weekly, 1-hour IV infusions for 4 weeks[1]

1 TREATMENT CYCLE = 4 INFUSIONS (10 mg/kg each)

1-hour infusion per week for 4 weeks[1]



SUBSEQUENT TREATMENT CYCLES

Administer subsequent treatment cycles based on clinical evaluation[1]

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

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.

gMG=generalized myasthenia gravis.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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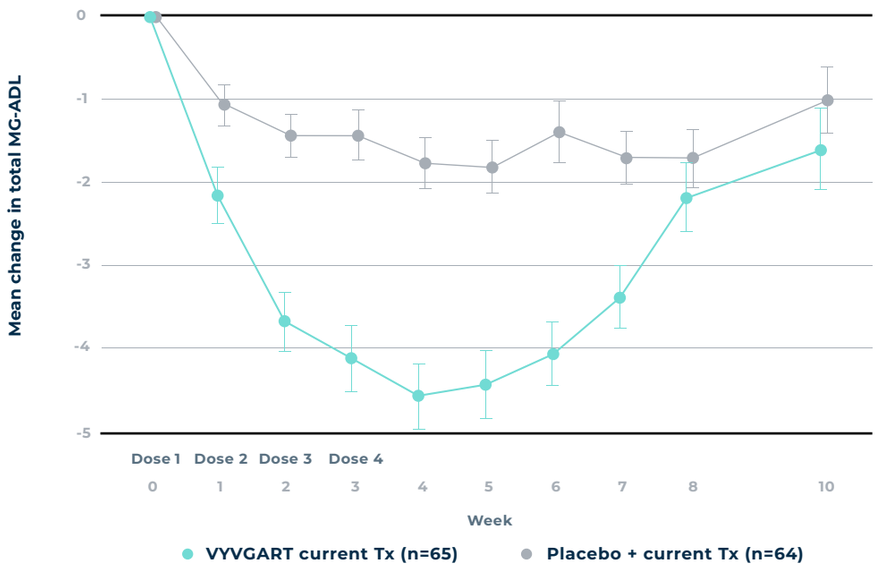
Mean change in MG-ADL from baseline over time in the ADAPT clinical trial (first treatment cycle)[1,5]*



*Clinical trial data from the anti-AChR antibody positive VYVGART-treated population.
AChR=acetylcholine receptor; MG-ADL=Myasthenia Gravis Activities of Daily Living; Tx=treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

Lactation

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

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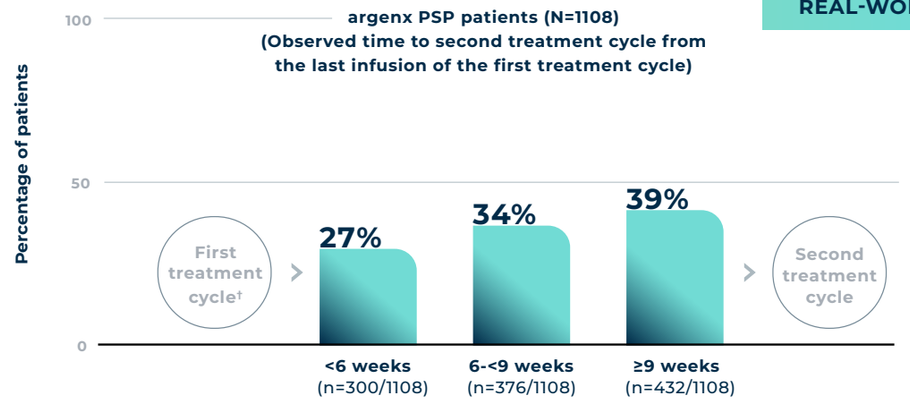
Observational real-world data: distribution of time to the second treatment cycle for patients on VYVGART[1,14]

REAL-WORLD DATA



In the ADAPT clinical trial, the minimum time between treatment cycles, specified by study protocol, was 4 weeks from the last infusion.

Study Limitations: This real-world data comes from a retrospective, observational study self-reported by patients who were enrolled in argenx's Patient Support Program from December 2021 to January 23, 2023, and was collected by argenx-employed Nurse Case Managers. Results were validated by comparison to actual dispense data reported by specialty pharmacies. The data, which looked at patients who completed 1 treatment cycle and initiated a second cycle, should not be extrapolated to apply to subsequent cycles. This data should not be used as a substitute for conducting a clinical evaluation of each individual patient.

†Most patients completed the first treatment cycle within 21 days (1 dose every week for 4 weeks).
PSP=Patient Support Program.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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VYVGART: broad access and personalized support

DID YOU KNOW

~85%

of US commercial and Medicare patients have a published **VYVGART** policy?[12]*

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

*Policy reporter data as of September 2022.

Get personalized support for you and your patients with **My VYVGART® Path**

- Benefit verification and access support
- Information about potential financial assistance programs
- Referrals to local and national myasthenia gravis resources and organizations

To get patients started with VYVGART, visit VYVGARTHCP.com/enroll

References: 1. VYVGART. Prescribing information. argenx US Inc; 2022. **2.** Wolfe GI et al. *J Neurol Sci*. 2021;430:118074. doi:10.1016/j.jns.2021.118074 **3.** Koneczny I, Herbst R. *Cells*. 2019;8(7):671. doi:10.3390/cells8070671 **4.** Howard JF Jr et al. *Neurology*. 2019;92(23):e2661-e2673. doi:10.1212/WNL.0000000000007600 **5.** Howard JF Jr et al. *Lancet Neurol*. 2021;20(7):526-536. doi:10.1016/S1474-4422(21)00159-9 **6.** Roopenian DC, Akilesh S. *Nat Rev Immunol*. 2007;7(9):715-725. doi:10.1038/nri2155 **7.** Ward ES, Ober RJ. *Trends Pharmacol Sci*. 2018;39(10):892-904. doi:10.1016/j.tips.2018.07.007 **8.** Gilhus NE et al. *Nat Rev Neurol*. 2016;12(5):259-268. doi:10.1038/nrneurol.2016.44 **9.** Huijbers MG et al. *J Intern Med*. 2014;275(1):12-26. doi:10.1111/joim.12163 **10.** Mantegazza R et al. *Neuropsychiatr Dis Treat*. 2011;7:151-160. doi:10.2147/NDT.S8915 **11.** Ulrichts P et al. *J Clin Invest*. 2018;128(10):4372-4386. doi:10.1172/JCI97911 **12.** Data on file, argenx US Inc. March 2023. **13.** Wolfe GI et al. *Neurology*. 1999;52(7):1487-1489. doi:10.1212/wnl.52.7.1487 **14.** Qi C et al. Poster presented at: 45th Annual Carrell-Krusen Neuromuscular Symposium; February 23–24, 2023. Dallas, TX.

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

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.

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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 infection (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 is 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.

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.

Hypersensitivity Reactions

Hypersensitivity reactions, including rash, angioedema, and dyspnea, were observed with VYVGART. 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 during administration and for 1 hour thereafter for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs during administration, discontinue VYVGART infusion and institute appropriate supportive measures if needed.

ADVERSE REACTIONS

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 VYVGART 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 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).

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

VYVGART—the first and only IgG Fc-antibody fragment for the treatment of gMG in adult patients who are anti-AChR antibody positive[1,2]

IMPROVEMENT IN DAILY FUNCTION

68% (n=44/65) of anti-AChR antibody positive patients treated with VYVGART were responders who experienced improvement in daily function (MG-ADL) vs **30% (n=19/64)** with placebo **(*P*<0.0001)**[1,5*†]

REDUCTION IN MUSCLE WEAKNESS

63% (n=41/65) of anti-AChR antibody positive patients treated with VYVGART were responders who experienced reduction in muscle weakness (QMG) during the first treatment cycle vs **14% (n=19/62)** with placebo **(*P*<0.0001)**[1,5*‡]

DEMONSTRATED SAFETY PROFILE IN THE ADAPT CLINICAL TRIAL

The most common ARs observed in the clinical trial 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%)[1§]

The majority of infections and hematologic abnormalities were mild to moderate in severity[1]

Visit VYVGARTHCP.com to see how VYVGART may help

*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 ≥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.
AChR=acetylcholine receptor; AR=adverse reaction; Fc=fragment, crystallized; gMG=generalized myasthenia gravis; IgG=immunoglobulin G; MG-ADL=Myasthenia Gravis Activities of Daily Living; QMG=Quantitative Myasthenia Gravis.

IMPORTANT SAFETY INFORMATION (cont'd)

Infection (cont'd)

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 is 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.

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

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