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

Picture your life in motion

GENERALIZED MYASTHENIA GRAVIS

doesn't get to steal this moment

Getting started with VYVGART

What is VYVGART® (efgartigimod alfa-fcab)?

VYVGART is a prescription medicine used to treat a condition called generalized myasthenia gravis, which causes muscles to tire and weaken easily throughout the body, in adults who are positive for antibodies directed toward a protein called acetylcholine receptor (anti-AChR antibody positive).

SELECT IMPORTANT SAFETY INFORMATION

VYVGART may increase the risk of infection. In a clinical study, the most common infections were urinary tract and respiratory tract infections.

Please see Important Safety Information throughout. Please see accompanying full Prescribing Information or visit VYVGART.com/PI.

ABOUT GENERALIZED MYASTHENIA GRAVIS

Generalized myasthenia gravis (gMG) is a rare neuromuscular disease that causes muscle weakness and fatigue

MUSCLE WEAKNESS FROM gMG CAN CAUSE:

- Eyelid drooping
- Blurred or double vision
- Difficulty speaking
- Difficulty chewing/swallowing
- Choking
- Difficulty supporting neck
- Shortness of breath/difficulty breathing
- Weakness in the arms and legs
- Difficulty walking/standing

gMG symptoms can make daily life more challenging and may limit one's ability to do everyday activities

UNDERSTANDING HARMFUL AChR ANTIBODIES IS AN IMPORTANT PART OF UNDERSTANDING gMG

Antibodies, also known as immunoglobulins (Ig), are proteins produced by the immune system to help **protect the body from infection and disease**.

The immune system makes **5 different types of antibodies (IgG, IgA, IgE, IgD, IgM)**, each with a distinct role in protecting the body.

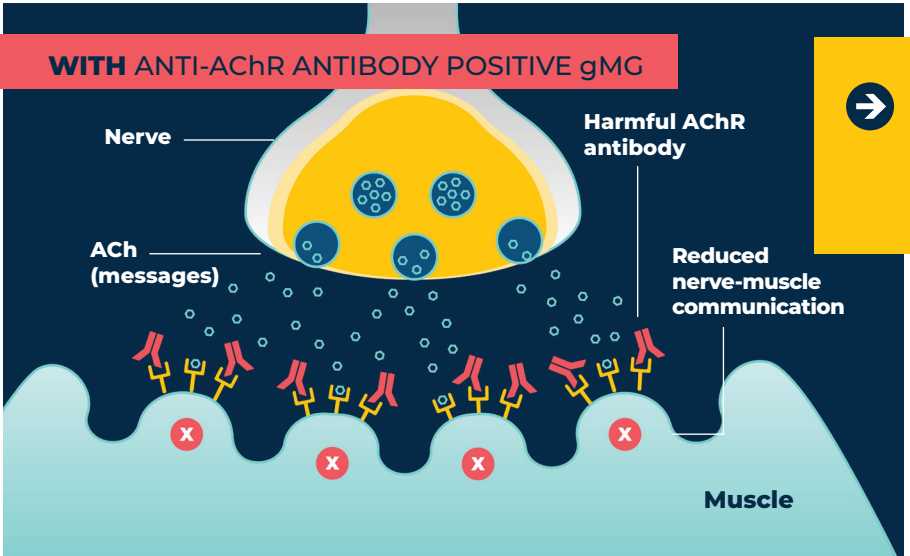
IgG is the most common type of antibody in the human body. Sometimes the immune system mistakenly makes IgG antibodies that target AChR (receptors). These are known as harmful AChR antibodies. Patients with harmful AChR antibodies have **anti-AChR antibody positive gMG**.

AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; IgG=immunoglobulin G
See pages 12 and 13 for a glossary of terms.

HARMFUL AChR ANTIBODIES CAUSE gMG SYMPTOMS

While IgG antibodies continue to protect the body, **harmful AChR antibodies disrupt communication between muscles and nerves**.

This **prevents muscles from getting some messages sent by nerves**; this is what causes gMG symptoms.



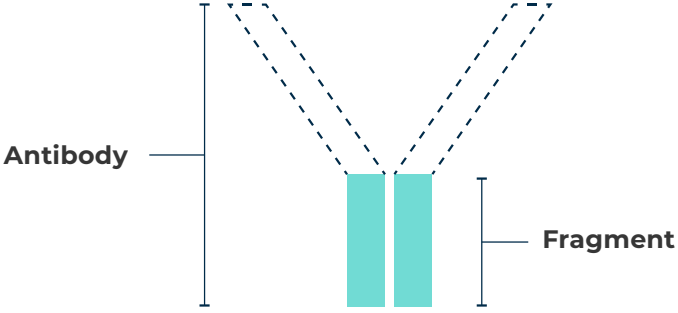
Learn more about harmful AChR antibodies and gMG at ABOUTgMG.com

ACh=acetylcholine; AChR=acetylcholine receptor
See pages 12 and 13 for a glossary of terms.

GENERALIZED
MYASTHENIA GRAVIS
doesn't get to stop this cheering section

ABOUT VYVGART

VYVGART is the first and only FDA-approved treatment that uses a fragment of an IgG antibody to treat adults with anti-AChR antibody positive gMG



VYVGART is a fragment of an IgG antibody.

VYVGART is specifically designed to attach to and block the neonatal Fc receptor (FcRn), **resulting in the reduction of IgG antibodies, including the harmful AChR antibodies** that cause gMG symptoms.

VYVGART specifically works to reduce IgG antibodies, including gMG-causing, harmful AChR antibodies.

AChR=acetylcholine receptor; FcRn=neonatal Fc receptor; gMG=generalized myasthenia gravis; IgG=immunoglobulin G
See pages 12 and 13 for a glossary of terms.

SELECT IMPORTANT SAFETY INFORMATION

More patients on VYVGART vs placebo had below normal levels for white blood cell counts, lymphocyte counts, and neutrophil counts. The majority of infections and blood side effects were mild to moderate in severity. Your health care provider should check you for infections before starting treatment, during treatment, and after treatment with VYVGART.

Please see Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit VYVGART.com/PI.

Because of VYVGART (efgartigimod alfa-fcab), IgG antibodies are reduced, including the harmful AChR antibodies that cause gMG symptoms

Receptors called “FcRn” extend the life of IgG antibodies. In gMG, this allows harmful AChR antibodies to continue causing gMG symptoms. But IgG antibodies, including harmful AChR antibodies, that cannot attach to an FcRn are removed by the body. When harmful AChR antibodies that cause gMG symptoms are removed, they can no longer disrupt nerve-muscle communication.

It’s like trying to get a table at a busy restaurant, where FcRns are the tables. IgG antibodies that get a table can stay for dinner, but if there are no tables available, IgG antibodies have to leave. The same goes for VYVGART, but **since VYVGART can take some tables, there are fewer tables available for IgG antibodies, including harmful AChR antibodies**. Those who don’t get a table are then removed.

AChR=acetylcholine receptor; FcRn=neonatal Fc receptor; gMG=generalized myasthenia gravis; IgG=immunoglobulin G
See pages 12 and 13 for a glossary of terms.

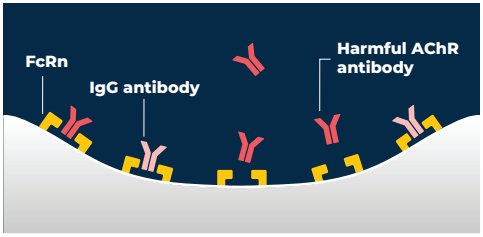
SELECT IMPORTANT SAFETY INFORMATION

Tell your health care provider if you have any history of infections. Tell your health care provider right away if you have signs or symptoms of an infection during treatment with VYVGART such as fever, chills, frequent and/or painful urination, cough, pain and blockage of nasal passages/sinus, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain.

Please see Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit VYVGART.com/PI.

ANTI-AChR ANTIBODY POSITIVE gMG

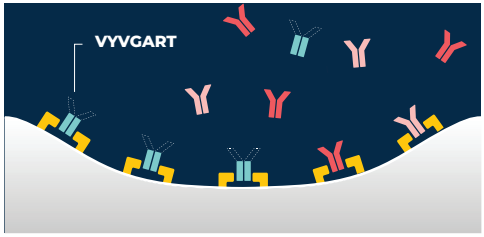
IgG antibodies attach to FcRn to **avoid being removed by the body**. In gMG, this allows harmful AChR antibodies to stay in the body longer.



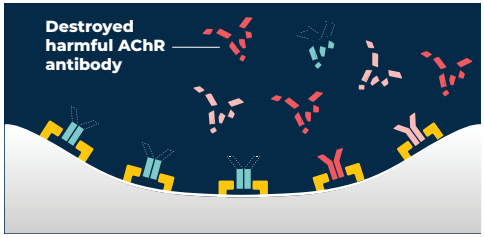
When harmful AChR antibodies are able to attach to FcRns, **fewer are destroyed** by the body. These harmful AChR antibodies remain in the body and **continue to cause gMG symptoms**.

ANTI-AChR ANTIBODY POSITIVE gMG WITH VYVGART

VYVGART targets FcRn receptors, **preventing many IgG antibodies, including the harmful** AChR antibodies, **from attaching**.



Harmful AChR antibodies that do not attach to FcRns are **removed from the body and can no longer cause gMG symptoms**.



AChR=acetylcholine receptor; FcRn=neonatal Fc receptor; gMG=generalized myasthenia gravis; IgG=immunoglobulin G
See pages 12 and 13 for a glossary of terms.

SELECT IMPORTANT SAFETY INFORMATION

VYVGART can cause the immune system to have undesirable reactions such as rashes, swelling under the skin, and shortness of breath. In clinical studies, the reactions were mild or moderate and occurred within 1 hour to 3 weeks of administration, and the reactions did not lead to VYVGART discontinuation. Your health care provider should monitor you during and after treatment and discontinue VYVGART if needed. Tell your health care provider immediately about any undesirable reactions.

Please see Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit VYVGART.com/PI.

EFFECTIVENESS

When added to their current gMG treatment, VYVGART (efgartigimod alfa-fcab) helped clinical trial participants with anti-AChR antibody positive gMG achieve:

Improved daily abilities

68% (44 of 65) of participants on VYVGART achieved significant improvement in their ability to perform daily activities*

Compared to 30% (19 of 64) of participants on placebo plus current treatment

Reduced muscle weakness

63% (41 of 65) of participants on VYVGART achieved a significant reduction in muscle weakness†

Compared to 14% (9 of 64) of participants on placebo plus current treatment

VYVGART was evaluated in a global clinical trial of adults with anti-AChR antibody positive gMG.

The clinical trial examined the safety and efficacy of VYVGART in 167 adults (18 years or older‡) with gMG. In addition to their current treatment, participants received either VYVGART or a placebo.

*Improvement maintained for 4 or more weeks was measured by a decrease of 2 or more points on the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale, with the first reduction occurring no later than 1 week after the last infusion of treatment cycle 1. The MG-ADL scale assesses the impact of gMG on daily functions by measuring 8 signs or symptoms that are commonly affected in gMG. Each item is measured on a 4-point scale, where a score of 0 represents normal function and a score of 3 represents the loss of ability to perform that function. Total scores range from 0 to 24 points, with a higher score showing more severe gMG.

†Improvement maintained for 4 or more weeks was measured by a decrease of 3 or more points on the Quantitative Myasthenia Gravis (QMG) scale, with the first reduction occurring no later than 1 week after the last infusion of treatment cycle 1. The QMG scale assesses muscle weakness in gMG based on 13 items. Each item is assessed on a 4-point scale, where a score of 0 represents no muscle weakness and a score of 3 represents severe muscle weakness. Total scores range from 0 to 39, with a higher score meaning muscle weakness is more severe.

‡Participants in Japan were 20 years or older.

AChR=acetylcholine receptor; gMG=generalized myasthenia gravis

See pages 12 and 13 for a glossary of terms.

SELECT IMPORTANT SAFETY INFORMATION

The most common side effects of VYVGART are respiratory tract infection, headache, and urinary tract infection. These are not all the possible side effects of VYVGART. Call your doctor for medical advice about side effects.

Please see Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit VYVGART.com/PI.

VYVGART was safe in treating most clinical trial participants

In the clinical trial, the following side effects were reported in at least 5% of participants on VYVGART and more frequently than in participants on placebo

Side Effect	VYVGART 84 participants (%)	Placebo 83 participants (%)
Respiratory tract infection	33%	29%
Headache	32%	29%
Urinary tract infection	10%	5%
Tingling sensation	7%	5%
Muscle pain	6%	1%

Most infections in participants on VYVGART were mild to moderate. Additionally, more patients on VYVGART vs placebo had blood side effects that were mild to moderate.

See pages 12 and 13 for a glossary of terms.

See more VYVGART clinical trial results at VYVGART.com

SELECT IMPORTANT SAFETY INFORMATION

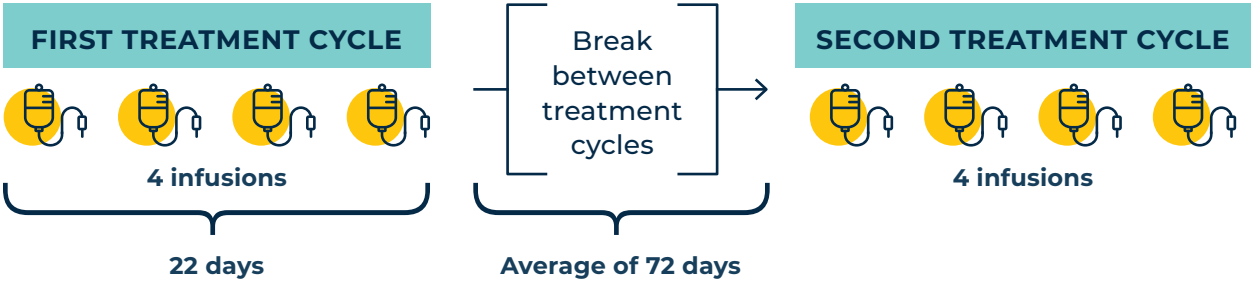
VYVGART may increase the risk of infection. In a clinical study, the most common infections were urinary tract and respiratory tract infections.

Please see Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit VYVGART.com/PI.

VYVGART (efgartigimod alfa-fcab) is given in treatment cycles with a break between each cycle*

A treatment cycle consists of a 1-hour infusion each week for 4 weeks (4 infusions total)

In the clinical trial, the average time between the first infusion of the first treatment cycle and the first infusion of the second treatment cycle was **94 days**.



> *Your next treatment cycle is based on your neurologist's evaluation of your gMG symptoms and any side effects after treatment.* The minimum time between treatment cycles in the clinical study was 50 days.*

AChR=acetylcholine receptor; gMG=generalized myasthenia gravis
*If additional cycles are needed.

SELECT IMPORTANT SAFETY INFORMATION

More patients on VYVGART vs placebo had below normal levels for white blood cell counts, lymphocyte counts, and neutrophil counts. The majority of infections and blood side effects were mild to moderate in severity. Your health care provider should check you for infections before starting treatment, during treatment, and after treatment with VYVGART.

Please see Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit VYVGART.com/PI.

Track your symptoms to help your neurologist determine your next treatment cycle

Download the MG-ADL assessment tool on VYVGART.com to start tracking your symptoms. If you are enrolled in My VYVGART Path, a physical journal will be mailed to you and a Nurse Case Manager can show you how to use it as you get started.

Your neurologist will work with you to help determine if and when you need another treatment cycle, with the aim to **help manage your symptoms**.*

*If additional cycles are needed.
See pages 12 and 13 for a glossary of terms.

3 ways to find the infusion center nearest to you

1. **Reach out** to your doctor's office
2. Search the Infusion Center Locator at **VYVGART.com**
3. Call **1-833-MY-PATH-1 (1-833-697-2841)** to speak to someone

Find out more about VYVGART treatment cycles and learn how to track your symptoms on VYVGART.com

SELECT IMPORTANT SAFETY INFORMATION

Tell your health care provider if you have any history of infections. Tell your health care provider right away if you have signs or symptoms of an infection during treatment with VYVGART such as fever, chills, frequent and/or painful urination, cough, pain and blockage of nasal passages/sinus, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain.

Please see Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit VYVGART.com/PI.

My VYVGART® Path

Here for you during your VYVGART (efgartigimod alfa-fcab) treatment journey

My VYVGART Path is a Patient Support Program that provides **personalized support** from a Nurse Case Manager and committed support team. They're knowledgeable about VYVGART and are dedicated to listening to you and helping you navigate your VYVGART treatment journey.

A Nurse Case Manager can help you:

Understand your VYVGART treatment

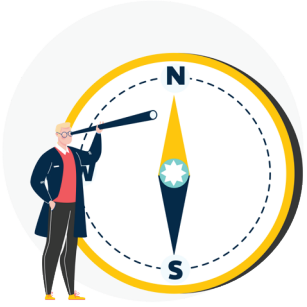
A Nurse Case Manager can provide educational information about VYVGART.

Feel empowered with resources and information

Nurse Case Managers can support you throughout your VYVGART treatment journey to help you in following your doctor's treatment plan.

Please see Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit VYVGART.com/PI.

To get started, ask your neurologist to enroll you in My VYVGART Path. Visit myVYVGARTpath.com to learn more.



Navigate the insurance process

You may have questions about your insurance coverage, want to know more about the cost of treatment, or just need information about your out-of-pocket costs for VYVGART. With My VYVGART Path, you'll find support in understanding each step of the insurance process.

Understand potential financial assistance programs

If you have financial concerns or gaps in insurance coverage for your VYVGART therapy, a Nurse Case Manager is here for you with information and support.

Terms and Definitions

Acetylcholine (ACh) – Acetylcholine helps carry messages from the brain to different parts of the body, including muscles. In gMG, harmful AChR antibodies damage the receptors for acetylcholine on muscles, which causes muscle weakness.

Acetylcholine receptor (AChR) – A type of receptor (message receiver) found on muscles. These receptors receive messages from nerves that tell muscles what to do. Patients with gMG who have antibodies that damage AChR (receptors) are called anti-AChR antibody positive gMG patients. Anti-AChR antibody positive is the most common type of gMG.

Acetylcholine receptor (AChR) antibody – Sometimes the immune system mistakenly makes IgG antibodies that target AChR (receptors). These are known as harmful AChR antibodies. gMG patients with harmful AChR antibodies have anti-AChR antibody positive gMG.

Anti-AChR antibody positive gMG – The most common type of gMG. People with gMG who have harmful antibodies that damage acetylcholine receptors (AChR) are called anti-AChR antibody positive gMG patients.

Antibody fragment – An antibody fragment is only part of a whole antibody. For example, the bottom section of the Y-shaped antibody is a fragment.

Biologics – Biologics treat disease by using substances made from living organisms. These substances may naturally occur in the body or may be artificially created. A biologic must be approved by the Food and Drug Administration (FDA) to be used as a treatment in the United States.

Clinical trial – A type of research that tests the safety and effectiveness of a treatment in people. The FDA reviews the results of clinical trials to determine if a treatment is safe and effective for use in a specific condition.

Immunoglobulin G (IgG) antibody – A Y-shaped protein made by the immune system. Antibodies attach to different things to let the immune system know

Here's a list of commonly used terms related to generalized myasthenia gravis (gMG) that may help you and your loved ones better understand gMG.

that there is a potential threat that it will need to destroy or neutralize. Antibodies can attach to disease-causing substances like bacteria and viruses.

Immunosuppressive therapy (IST) – A type of medication used to reduce the strength of the body's immune system. It is often used to treat conditions where the immune system is overactive, like in autoimmune diseases.

MG-ADL scale – The Myasthenia Gravis Activities of Daily Living (MG-ADL) scale assesses the impact of gMG on daily functions by measuring 8 signs or symptoms that are commonly affected in gMG: the ability to speak, chew, swallow, breathe, brush teeth or comb hair, and get out of a chair, as well as the frequency of double vision and eyelid droop. Each item is measured on a 4-point scale, where a score of 0 represents normal function and a score of 3 represents the loss of ability to perform that function. Total scores range from 0 to 24 points, with a higher score showing more severe gMG.

Neonatal Fc receptor (FcRn) – A receptor that attaches to IgG antibodies and helps them stay in the body longer. In gMG, the IgG antibodies and harmful AChR antibodies can both attach to FcRns to stay in the body longer.

Quantitative Myasthenia Gravis (QMG) – The QMG scale assesses muscle weakness in gMG based on 13 items. Each item is assessed on a 4-point scale, where a score of 0 represents no muscle weakness and a score of 3 represents severe muscle weakness. Total scores range from 0 to 39, with a higher score meaning muscle weakness is more severe.

Find more common gMG terms and definitions at ABOUTgMG.com/glossary

Answers to other commonly asked questions about VYVGART (efgartigimod alfa-fcab)

Is VYVGART intended to be taken with other medications?

Yes, in the clinical trial, participants stayed on their current generalized myasthenia gravis (gMG) treatment while receiving VYVGART. Talk to your doctor about the medications you are taking as part of your treatment plan.

What are the most common side effects of VYVGART?

In 84 clinical trial participants treated with VYVGART, the most common side effects included respiratory tract infection (33%), headache (32%), urinary tract infection (10%), tingling sensation (7%), and muscle pain (6%).*

Most infections in participants on VYVGART were mild to moderate. Additionally, more patients on VYVGART vs placebo had blood side effects that were mild to moderate.

Do I have to get any vaccines before taking VYVGART?

Discuss with your doctor when you need to receive age-appropriate vaccines before starting a new treatment cycle with VYVGART. Some types of vaccines are not recommended while taking VYVGART. Be sure to talk to your doctor about vaccines before starting any treatment cycle of VYVGART.

How many of the trial participants continued on to the extended safety study?

91% of the clinical trial participants who were eligible chose to enter a 3-year extension safety study where they would receive VYVGART.

*In ≥5% treated with VYVGART and more frequently than placebo.

See pages 12 and 13 for a glossary of terms.

SELECT IMPORTANT SAFETY INFORMATION

VYVGART can cause the immune system to have undesirable reactions such as rashes, swelling under the skin, and shortness of breath. In clinical studies, the reactions were mild or moderate and occurred within 1 hour to 3 weeks of administration, and the reactions did not lead to VYVGART discontinuation. Your health care provider should monitor you during and after treatment and discontinue VYVGART if needed. Tell your health care provider immediately about any undesirable reactions.

Please see Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit VYVGART.com/PI.

More information available at VYVGART.com

What should I do if I miss an infusion?

If you miss a scheduled infusion, VYVGART may be administered up to 3 days after the scheduled infusion day. Work with your neurologist to reschedule your next infusion.

How do I track my symptoms?

Download the MG-ADL assessment tool on VYVGART.com to start tracking your symptoms. If you are enrolled in My VYVGART Path, a physical journal will be mailed to you and a Nurse Case Manager can show you how to use it as you get started.

How do I join the My VYVGART Path program?

After you and your neurologist decide on VYVGART, your doctor's office will be able to enroll you in My VYVGART Path. Then, a Nurse Case Manager will call, welcome you to the program, and offer assistance as you get started with VYVGART on your treatment journey.

SELECT IMPORTANT SAFETY INFORMATION

The most common side effects of VYVGART are respiratory tract infection, headache, and urinary tract infection. These are not all the possible side effects of VYVGART. Call your doctor for medical advice about side effects.

Please see Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit VYVGART.com/PI.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about VYVGART® (efgartigimod alfa-fcab)?

VYVGART may cause serious side effects, including:

- **Infection.** VYVGART may increase the risk of infection. In a clinical study, the most common infections were urinary tract and respiratory tract infections. More patients on VYVGART vs placebo had below normal levels for white blood cell counts, lymphocyte counts, and neutrophil counts. The majority of infections and blood side effects were mild to moderate in severity. Your health care provider should check you for infections before starting treatment, during treatment, and after treatment with VYVGART. Tell your health care provider if you have any history of infections. Tell your health care provider right away if you have signs or symptoms of an infection during treatment with VYVGART such as fever, chills, frequent and/or painful urination, cough, pain and blockage of nasal passages/sinus, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain.
- **Undesirable immune reactions (hypersensitivity reactions).** VYVGART can cause the immune system to have undesirable reactions such as rashes, swelling under the skin, and shortness of breath. In clinical studies, the reactions were mild or moderate and occurred within 1 hour to 3 weeks of administration, and the reactions did not lead to VYVGART discontinuation. Your health care provider should monitor you during and after treatment and discontinue VYVGART if needed. Tell your health care provider immediately about any undesirable reactions.

Before taking VYVGART, tell your health care provider about all of your medical conditions, including if you:

- Have a history of infection or you think you have an infection
- Have received or are scheduled to receive a vaccine (immunization). Discuss with your health care provider whether you need to receive age-appropriate immunizations before initiation of a new treatment cycle with VYVGART. The use of vaccines during VYVGART treatment has not been studied, and the safety with live or live-attenuated vaccines is unknown. Administration of live or live-attenuated vaccines is not recommended during treatment with VYVGART.
- Are pregnant or plan to become pregnant and are breastfeeding or plan to breastfeed.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the common side effects of VYVGART?

The most common side effects of VYVGART are respiratory tract infection, headache, and urinary tract infection.

These are not all the possible side effects of VYVGART. Call your doctor for medical advice about side effects. You may report side effects to the US Food and Drug Administration at 1-800-FDA-1088.

Please see the full Prescribing Information for VYVGART and talk to your doctor.

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

Picture your life in motion

- When added to their current gMG treatment, VYVGART helped most anti-AChR antibody positive clinical trial participants achieve **improved daily abilities***
- VYVGART was **safe in treating most clinical trial participants**. The most common side effects were respiratory tract infection, headache, and urinary tract infection. The majority of infections and blood side effects were mild to moderate in severity.

Talk to your neurologist to see if VYVGART is right for you

Use the camera on your smartphone to scan the QR code and download your VYVGART Doctor Discussion Guide.

*Improvement maintained for 4 or more weeks was measured by a decrease of 2 or more points on the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale, with the first reduction occurring no later than 1 week after the last infusion of treatment cycle 1. The MG-ADL scale assesses the impact of gMG on daily functions by measuring 8 signs or symptoms that are commonly affected in gMG. Each item is measured on a 4-point scale, where a score of 0 represents normal function and a score of 3 represents the loss of ability to perform that function. Total scores range from 0 to 24 points, with a higher score showing more severe gMG.

AChR=acetylcholine receptor; gMG=generalized myasthenia gravis
See pages 12 and 13 for a glossary of terms.

Call 1-833-VYVGART (1-833-898-4278) or visit VYVGART.com to find out more

SELECT IMPORTANT SAFETY INFORMATION

VYVGART may increase the risk of infection. In a clinical study, the most common infections were urinary tract and respiratory tract infections.

Please see Important Safety Information throughout.
Please see accompanying full Prescribing Information or visit VYVGART.com/PI.

argenx

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VYVGART safely and effectively. See full prescribing information for VYVGART.

VYVGART® (efgartigimod alfa-fcab) injection, for intravenous use
Initial U.S. Approval: 2021

----------INDICATIONS AND USAGE----------
VYVGART is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. (1)

----------DOSAGE AND ADMINISTRATION----------
- Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART. (2.1)
- The recommended dosage is 10 mg/kg administered as an intravenous infusion over one hour once weekly for 4 weeks. In patients weighing 120 kg or more, the recommended dose is 1200 mg per infusion. (2.2)
- Administer subsequent treatment cycles based on clinical evaluation; the safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established. (2.2)
- Must be diluted with 0.9% Sodium Chloride Injection, USP prior to administration. (2.3)
- Administer as an intravenous infusion over one hour via a 0.2 micron in-line filter. (2.3)

----------DOSAGE FORMS AND STRENGTHS----------
Injection: 400 mg in 20 mL (20 mg/mL) single-dose vial. (3)

----------CONTRAINDICATIONS----------
None. (4)

----------WARNINGS AND PRECAUTIONS----------
- Infections: Delay administration of VYVGART to patients with an active infection. Monitor for signs and symptoms of infection in patients treated with VYVGART. If serious infection occurs, administer appropriate treatment and consider withholding VYVGART until the infection has resolved. (5.1)
- Hypersensitivity Reactions: Angioedema, dyspnea, and rash have occurred. If a hypersensitivity reaction occurs, discontinue the infusion and institute appropriate therapy. (5.2)

----------ADVERSE REACTIONS----------
Most common adverse reactions (≥ 10%) in patients treated with gMG are respiratory tract infections, headache, and urinary tract infection. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact argenx at 1-833-argx411 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
Closely monitor for reduced effectiveness of medications that bind to the human neonatal Fc receptor. When concomitant long-term use of such medications is essential for patient care, consider discontinuing VYVGART and using alternative therapies. (7)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 04/2022

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Vaccination

Because VYVGART causes transient reduction in IgG levels, immunization with live-attenuated or live vaccines is not recommended during treatment with VYVGART. Evaluate the need to administer age-appropriate immunizations according to immunization guidelines before initiation of a new treatment cycle with VYVGART *[see Dosage and Administration (2.2) and Warnings and Precautions (5.1)]*.

2.2 Recommended Dose and Dose Schedules

Dilute VYVGART prior to administration. Administer via intravenous infusion only *[see Dosage and Administration (2.3)]*.

The recommended dosage of VYVGART is 10 mg/kg administered as an intravenous infusion over one hour once weekly for 4 weeks. In patients weighing 120 kg or more, the recommended dose of VYVGART is 1200 mg (3 vials) per infusion.

Administer subsequent treatment cycles based on clinical evaluation. The safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.

If a scheduled infusion is missed, VYVGART may be administered up to 3 days after the scheduled time point. Thereafter, resume the original dosing schedule until the treatment cycle is completed.

2.3 Preparation and Administration Instructions

Prior to administration, VYVGART single-dose vials require dilution in 0.9% Sodium Chloride Injection, USP, to make a total volume to be administered of 125 mL *(see Preparation)*.

Check that the VYVGART solution is clear to slightly opalescent and colorless to slightly yellow. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if opaque particles, discoloration, or other foreign particles are present.

Use aseptic technique when preparing the VYVGART diluted solution for intravenous infusion. Each vial is for single-dose only.

Discard any unused portion.

Preparation

- Calculate the dose (mg), total drug volume (mL) of VYVGART solution required, and the number of vials needed based on the recommended dose according to the patient's body weight *[see Dosage and Administration (2.2)]*. Each vial contains a total of 400 mg of VYVGART at a concentration of 20 mg per mL.
- Gently withdraw the calculated dose of VYVGART from the vial(s) with a sterile syringe and needle. Discard any unused portion of the vials.
- Dilute the withdrawn VYVGART with 0.9% Sodium Chloride Injection, USP to make a total volume of 125 mL for intravenous infusion.
- Gently invert the infusion bag containing the diluted VYVGART without shaking to ensure thorough mixing of the product and the diluent.
- The diluted solution can be administered using polyethylene (PE), polyvinyl chloride (PVC), ethylene vinyl acetate (EVA), or ethylene/polypropylene copolymer bags (polyolefins bags), and with PE, PVC, EVA, or polyurethane/polypropylene infusion lines.

Storage Conditions of the Diluted Solution

- VYVGART does not contain preservatives. Administer immediately after dilution and complete the infusion within 4 hours of dilution.
- If immediate use is not possible, the diluted solution may be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 8 hours. Do not freeze. Protect from light. Allow the diluted drug to reach room temperature before administration. Complete the infusion within 4 hours of removal from the refrigerator. Do not heat the diluted drug in any manner other than via ambient air.

Administration

- VYVGART should be administered via intravenous infusion by a healthcare professional.
- Visually inspect VYVGART diluted solution for particles or discoloration prior to administration. Do not use if it is discolored, or if opaque or foreign particles are seen.
- Infuse the total 125 mL of diluted solution intravenously over one hour via a 0.2 micron in-line filter.
- After administration of VYVGART, flush the entire line with 0.9% Sodium Chloride Injection, USP.
- 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 administration of VYVGART and institute appropriate supportive measures *[see Warnings and Precautions (5.2)].*
- Other medications should not be injected into infusion side ports or mixed with VYVGART.

3 DOSAGE FORMS AND STRENGTHS

Injection: 400 mg/20 mL (20 mg/mL) as a colorless to slightly yellow, clear to slightly opalescent solution, in a single-dose vial.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Infections

VYVGART may increase the risk of infection. The most common infections observed in Study 1 were urinary tract infection (10% of VYVGART-treated patients compared to 5% of placebo-treated patients) and respiratory tract infections (33% of VYVGART-treated patients compared to 29% of placebo-treated patients) *[see Adverse Reactions (6.1) and Clinical Studies (14)]*. A higher frequency of patients who received VYVGART compared to placebo were observed to have below normal levels for white blood cell counts (12% versus 5%, respectively), lymphocyte counts (28% versus 19%, respectively), and neutrophil counts (13% versus 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. During treatment with VYVGART, 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 of immunization with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because VYVGART causes a reduction in IgG levels, vaccination with live-attenuated or live vaccines is not recommended during treatment with VYVGART. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART.

5.2 Hypersensitivity Reactions

Hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in VYVGART-treated patients. 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. Monitor patients during administration and for 1 hour thereafter for clinical signs and symptoms of hypersensitivity reactions *[see Dosage and Administration (2.3)]*. If a hypersensitivity reaction occurs during administration, discontinue VYVGART infusion and institute appropriate supportive measures if needed.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Infections *[see Warnings and Precautions (5.1)]*
- Hypersensitivity Reactions *[see Warnings and Precautions (5.2)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical studies, the safety of VYVGART has been evaluated in 246 patients who received at least one dose of VYVGART, including 57 patients exposed to at least 7 treatment cycles and 8 patients exposed to at least 10 treatment cycles.

In a placebo-controlled study (Study 1) in patients with gMG, 84 patients received VYVGART 10 mg/kg *[see Clinical Studies (14)]*. Of these 84 patients, approximately 75% were female, 82% were White, 11% were Asian, and 8% were of Hispanic or Latino ethnicity. The mean age at study entry was 46 years (range 19 to 78).

The minimum time between treatment cycles, specified by study protocol, was 50 days. On average, VYVGART-treated patients received 2 cycles in Study 1. The mean and median times to the second treatment cycle were 94 days and 72 days from the initial infusion of the first treatment cycle, respectively, for VYVGART-treated patients.

Adverse reactions reported in at least 5% of patients treated with VYVGART and more frequently than placebo are summarized in Table 1. The most common adverse reactions (reported in at least 10% of VYVGART-treated patients) were respiratory tract infection, headache, and urinary tract infection.

Table 1: Adverse Reactions in ≥ 5% of Patients Treated with VYVGART and More Frequently than in Placebo-Treated Patients in Study 1 (Safety Population)

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.*

6.2 Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to VYVGART in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.

In up to 26 weeks of treatment in Study 1, 20% (17/83) of patients developed antibodies to VYVGART. Seven percent (6/83) of patients developed neutralizing antibodies.

Because few patients tested positive for anti-efgartigimod alfa-fcab antibodies and neutralizing antibodies, the available data are too limited to make definitive conclusions regarding immunogenicity and the effect on pharmacokinetics, safety, or efficacy of VYVGART.

7 DRUG INTERACTIONS

7.1 Effect of VYVGART on Other Drugs

Concomitant use of VYVGART with medications that bind to the human neonatal Fc receptor (FcRn) (e.g., immunoglobulin products, monoclonal antibodies, or antibody derivates containing the human Fc domain of the IgG subclass) may lower systemic exposures and reduce effectiveness of such medications. Closely monitor for reduced effectiveness of medications that bind to the human neonatal Fc receptor. When concomitant long-term use of such medications is essential for patient care, consider discontinuing VYVGART and using alternative therapies.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on the use of VYVGART during pregnancy. There is no evidence of adverse developmental outcomes following the administration of VYVGART at up to 100 mg/kg/day in rats and rabbits (see Data).

The background rate of major birth defects and miscarriage in the indicated population is unknown. In the U.S. general population, the estimated background rate of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Monoclonal antibodies are increasingly transported across the placenta as pregnancy progresses, with the largest amount transferred during the third trimester. Therefore, efgartigimod alfa-fcab may be transmitted from the mother to the developing fetus.

As VYVGART is 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 or live-attenuated vaccines to infants exposed to VYVGART in utero *[see Warnings and Precautions (5.1)].*

Data

Animal Data

Intravenous administration of efgartigimod alfa-fcab (0, 30, or 100 mg/kg/day) to pregnant rats and rabbits throughout organogenesis resulted in no adverse effects on embryofetal development in either species. The doses tested are 3 and 10 times the recommended human dose (RHD) of 10 mg/kg, on a body weight (mg/kg) basis.

Intravenous administration of efgartigimod alfa-fcab (0, 30, or 100 mg/kg/day) to rats throughout gestation and lactation resulted in no adverse effects on pre- or postnatal development. The doses tested are 3 and 10 times the recommended human dose (RHD) of 10 mg/kg, on a body weight (mg/kg) basis.

8.2 Lactation

Risk Summary

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.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Clinical studies of VYVGART did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently from younger adult patients.

8.6 Renal Impairment

No dose adjustment of VYVGART is needed for patients with mild renal impairment. There are insufficient data to evaluate the impact of moderate renal impairment (eGFR 30-59 mL/min/1.73 m^2)

and severe renal impairment (eGFR <30 mL/min/1.73 m²) on pharmacokinetic parameters of efgartigimod alfa-fcab *[see Clinical Pharmacology (12.3)].*

11 DESCRIPTION

Efgartigimod alfa-fcab is a human immunoglobulin G1 (IgG1) -derived Fc fragment (fragment, crystallized) of the za allotype. The efgartigimod alfa-fcab Fc fragment is a homodimer consisting of two identical peptide chains each consisting of 227 amino acids linked together by two interchain disulfide bonds with affinity for FcRn. The molecular weight of efgartigimod alfa-fcab is approximately 54 kDa.

VYVGART (efgartigimod alfa-fcab) injection is a sterile, preservative free, clear to slightly opalescent, colorless to slightly yellow solution supplied in a single-dose vial for infusion after dilution.

Each 20 mL single-dose vial contains 400 mg of efgartigimod alfa-fcab at a concentration of 20 mg/mL. In addition, each mL of solution contains L-arginine hydrochloride (31.6 mg), polysorbate 80 (0.2 mg), sodium chloride (5.8 mg), sodium phosphate dibasic anhydrous (2.4 mg), sodium phosphate monobasic monohydrate (1.1 mg) and water for injection, USP, at a pH of 6.7.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

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

12.2 Pharmacodynamics

In Study 1 *[see Clinical Studies (14)],* the pharmacological effect of efgartigimod alfa-fcab was assessed by measuring the decrease in serum IgG levels and AChR autoantibody levels. In patients testing positive for AChR antibodies and who were treated with VYVGART, there was a reduction in total IgG levels relative to baseline. Decrease in AChR autoantibody levels followed a similar pattern.

12.3 Pharmacokinetics

Efgartigimod alfa-fcab exhibits linear pharmacokinetics, and following single doses of efgartigimod alfa-fcab, exposures increase proportionally up to 50 mg/kg (5 times the recommended dosage).

Distribution

The volume of distribution is 15 to 20L.

Metabolism and Elimination

Efgartigimod alfa-fcab is expected to be degraded by proteolytic enzymes into small peptides and amino acids.

The terminal half-life is 80 to 120 hours (3 to 5 days).

After a single intravenous dose of 10 mg/kg efgartigimod alfa-fcab in healthy subjects, less than 0.1% of the administered dose was recovered in urine.

Specific Populations

Age, Sex, and Race

A population pharmacokinetics analysis assessing the effects of age, sex, and race did not suggest any clinically significant impact of these covariates on efgartigimod alfa-fcab exposures.

Patients with Renal Impairment

No dedicated pharmacokinetic study has been performed in patients with renal impairment.

A population PK analysis of data from the VYVGART clinical studies indicated that patients with mild renal impairment (eGFR 60-89 mL/min/1.72m²) had 22% increase in exposure relative to the exposure in patients with normal renal function *[see Use in Specific Populations (8.6)].*

Patients with Hepatic Impairment

No dedicated pharmacokinetic study has been performed in patients with hepatic impairment. Hepatic impairment is not expected to affect the pharmacokinetics of efgartigimod alfa-fcab.

Drug Interaction Studies

Clinical drug interactions studies have not been performed with efgartigimod alfa-fcab.

P450 Enzymes

Efgartigimod alfa-fcab is not metabolized by cytochrome P450 enzymes; therefore, interactions with concomitant medications that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely.

Drug Interactions with Other Drugs or Biological Products

Efgartigimod alfa-fcab may decrease concentrations of compounds that bind to the human FcRn *[see Drug Interactions (7.1)].*

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis and Mutagenesis

No studies have been conducted to assess the carcinogenic potential of efgartigimod alfa-fcab.

No studies have been conducted to assess the genotoxic potential of efgartigimod alfa-fcab.

Impairment of Fertility

Intravenous administration of efgartigimod alfa-fcab (0, 30, or 100 mg/kg/day) to male and female rats prior to and during mating and continuing in females through gestation day 7 resulted in no adverse effects on fertility. The doses tested are 3 and 10 times the recommended human dose (RHD) of 10 mg/kg, on a body weight (mg/kg) basis.

14 CLINICAL STUDIES

The efficacy of VYVGART for the treatment of generalized myasthenia gravis (gMG) in adults who are AChR antibody positive was established in a 26-week, multicenter, randomized, double-blind, placebo-controlled trial (Study 1; NCT03669588).

Study 1 enrolled patients who met the following criteria at screening:

- Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV
- MG-Activities of Daily Living (MG-ADL) total score of ≥ 5
- On stable dose of MG therapy prior to screening, that included acetylcholinesterase (AChE) inhibitors, steroids, or non-steroidal immunosuppressive therapies (NSISTs), either in combination or alone
- IgG levels of at least 6 g/L

A total of 167 patients were enrolled in Study 1 and were randomized to receive either VYVGART 10mg/kg (1200 mg for those weighing 120 kg or more) (n=84) or placebo (n=83). Baseline characteristics were similar between treatment groups. Patients had a median age of 46 years at screening (range: 19 to 81 years) and a median time since diagnosis of 9 years. Seventy-one percent were female, and 84% were White. Median MG-ADL total score was 9, and median Quantitative Myasthenia Gravis (QMG) total score was 16. The majority of patients (n=65 for VYVGART; n=64 for placebo) were positive for AChR antibodies.

At baseline, over 80% of patients in each group received AChE inhibitors, over 70% in each treatment group received steroids, and approximately 60% in each treatment group received NSISTs, at stable doses.

Patients were treated with VYVGART at the recommended dosage regimen *[see Dosage and Administration (2.2)]*.

The efficacy of VYVGART was measured using the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) which 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. In this study, an MG-ADL responder was defined as a patient with a 2-point or greater reduction in the total MG-ADL score compared to the treatment cycle baseline for at least 4 consecutive weeks, with the first reduction occurring no later than 1 week after the last infusion of the cycle.

The primary efficacy endpoint was the comparison of the percentage of MG-ADL responders during the first treatment cycle between treatment groups in the AChR-Ab positive population. A statistically

significant difference favoring VYVGART was observed in the MG-ADL responder rate during the first treatment cycle [67.7% in the VYVGART-treated group vs 29.7% in the placebo-treated group (p <0.0001)].

The efficacy of VYVGART was also measured using the Quantitative Myasthenia Gravis (QMG) total score which 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. In this study, a QMG responder was defined as a patient who had a 3-point or greater reduction in the total QMG score compared to the treatment cycle baseline for at least 4 consecutive weeks, with the first reduction occurring no later than 1 week after last infusion of the cycle.

The secondary endpoint was the comparison of the percentage of QMG responders during the first treatment cycle between both treatment groups in the AChR-Ab positive patients. A statistically significant difference favoring VYVGART was observed in the QMG responder rate during the first treatment cycle [63.1% in the VYVGART-treated group vs 14.1% in the placebo-treated group (p <0.0001)].

The results are presented in Table 2.

Table 2: MG-ADL and QMG Responders During Cycle 1 in AChR-Ab Positive Patients (mITT Analysis Set)

	VYVGART n=65 %	Placebo n=64 %	P-value	Odds Ratio (95% CI)
MG-ADL Responders	67.7	29.7	< 0.0001	4.951 (2.213, 11.528)
QMG Responders	63.1	14.1	< 0.0001	10.842 (4.179, 31.200)

MG-ADL=Myasthenia Gravis Activities of Daily Living; QMG =Quantitative Myasthenia Gravis; mITT=modified intent-to-treat; n=number of patients for whom the observation was reported; CI = confidence interval;
Logistic regression stratified for AChR-Ab status (if applicable), Japanese/Non-Japanese and standard of care, with baseline MG-ADL as covariate / QMG as covariates
Two-sided exact p-value

Figure 1 shows the mean change from baseline on the MG-ADL during cycle 1.

Figure 1: Mean Change in Total MG-ADL From Cycle 1 Baseline Over Time in AChR-Ab Positive Patients (mITT Analysis Set)

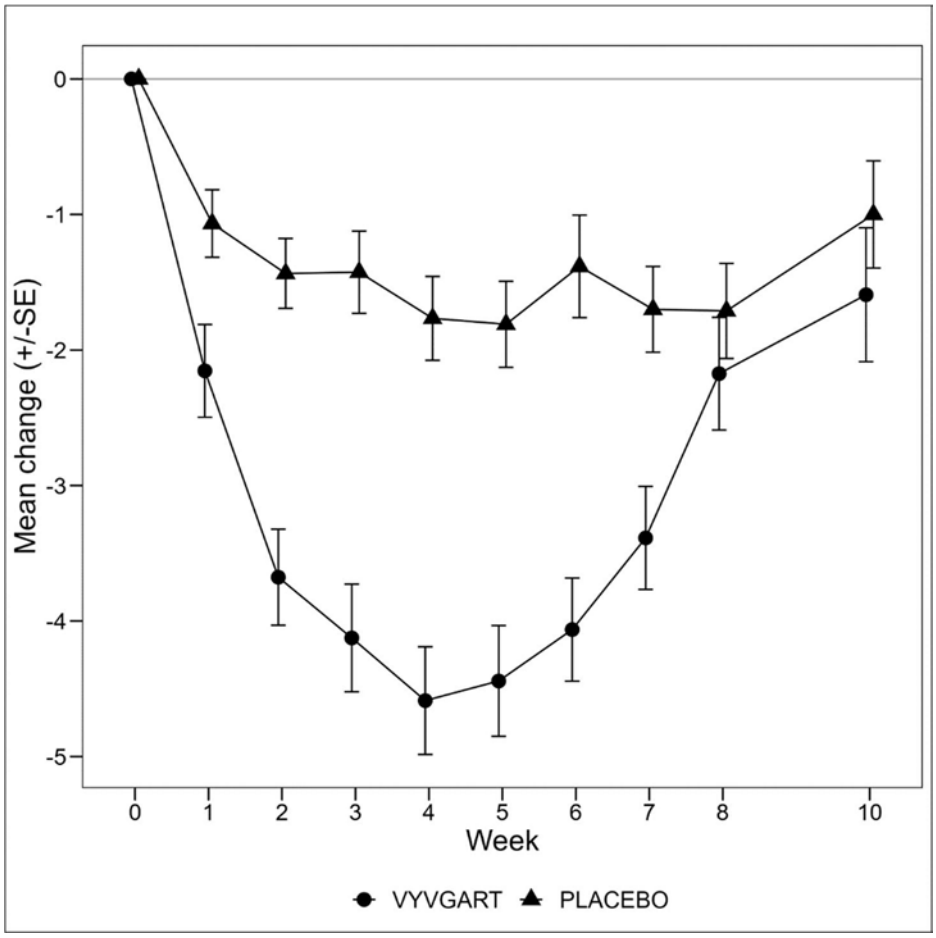
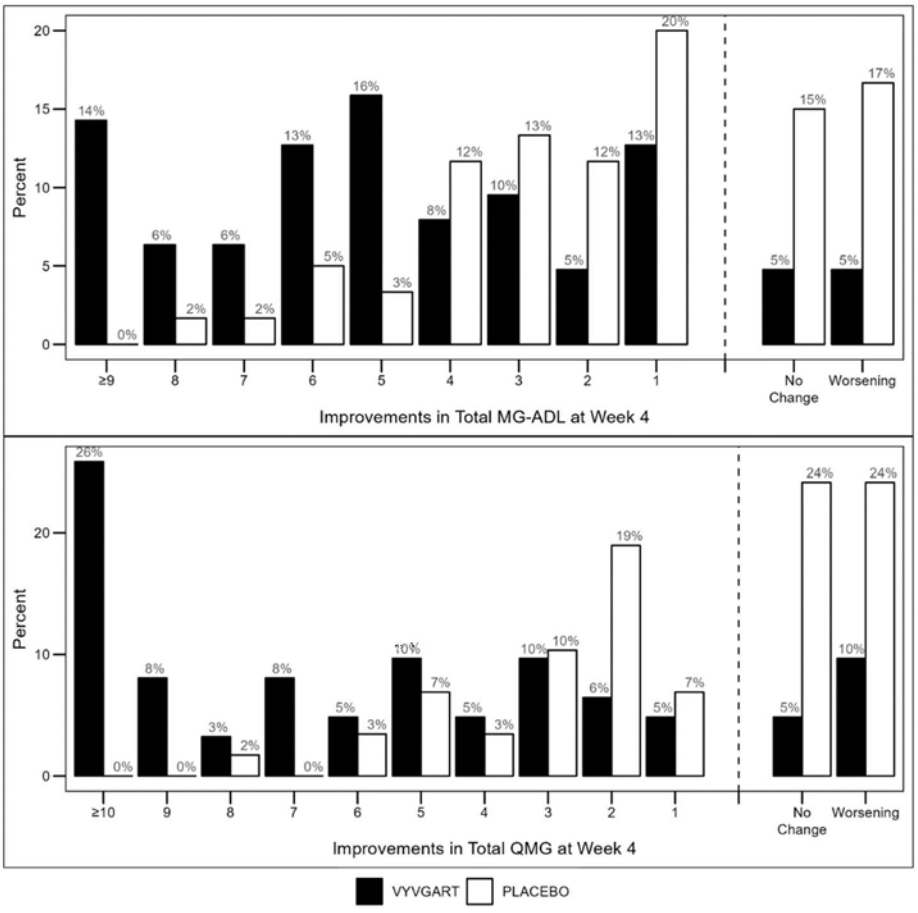


Figure 2 shows the distribution of response on the MG-ADL and QMG during cycle 1, four weeks after the first infusion with VYVGART.

Figure 2: Percentage of Patients with MG-ADL and QMG Total Score Change 4 Weeks Post Initial Infusion of the First Cycle in AChR-Ab Positive Population



16 HOW SUPPLIED/STORAGE AND HANDLING

VYVGART (efgartigimod alfa-fcab) injection is a preservative free, sterile, colorless to slightly yellow, clear to slightly opalescent solution supplied as 400 mg/20 mL (20 mg/mL) in one single-dose vial per carton (NDC 73475-3041-5).

Store VYVGART vials refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use. Do not freeze. Do not shake.

Refer to *Dosage and Administration (2.3)* for information on stability and storage of the diluted solutions of VYVGART.

17 PATIENT COUNSELING INFORMATION

Infections

Instruct patients to communicate any history of infections to the healthcare provider and to contact their healthcare provider if they develop any symptoms of an infection. Advise patients to complete age-appropriate vaccines according to immunization guidelines prior to initiation of a new treatment cycle with VYVGART. Administration of live or live-attenuated vaccines is not recommended during treatment with VYVGART *[see Warnings and Precautions (5.1)].*

Hypersensitivity Reactions

Inform patients about the signs and symptoms of hypersensitivity reactions. Advise patients to contact their healthcare provider immediately for signs or symptoms of hypersensitivity reactions *[see Warnings and Precautions (5.2)].*

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