VYVGART<sup>®</sup> Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) Subcitaneous Injection 180 mg/mL and 2000 U/mL/val (efgartigimod alfa-fcab) Injection for Intravenous Use 400 mg/20 mL vial

# DOCTOR Discussion Guide

#### Start the conversation about your anti-AChR antibody positive gMG symptoms and daily abilities

Fill out and bring this guide with you to your next appointment with your neurologist, and ask them if VYVGART could be right for you.

VYVGART for intravenous (IV) infusion and VYVGART Hytrulo for subcutaneous injection are both FDA-approved treatments for adults with anti-AChR antibody positive generalized myasthenia gravis (gMG).

AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; IV=intravenous

# What is VYVGART<sup>®</sup> (efgartigimod alfa-fcab) for intravenous (IV) infusion and what is VYVGART<sup>®</sup> HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection?

VYVGART and VYVGART HYTRULO are both prescription medicines, each 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 and VYVGART HYTRULO may increase the risk of infection. The most common infections for efgartigimod alfa-fcab-treated patients were urinary tract and respiratory tract infections.

# VYVGART Hytrulo could mean more time for you

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

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

### VYVGART Hytrulo offers a ~30 to 90 second subcutaneous injection



#### VYVGART Hytrulo can be given at an:







VYVGART for intravenous (IV) infusion is also available, and is given over 1 hour at an infusion center, doctor's office, or at home.\*<sup>†</sup>

\*For at least 30 minutes after your subcutaneous injection or 1 hour after your IV infusion, a healthcare professional will monitor you for reactions.

<sup>†</sup>In some cases, VYVGART Hytrulo for subcutaneous injection or VYVGART for IV infusion may also be given at home by a trained nurse.

gMG=generalized myasthenia gravis; IV=intravenous; MG-ADL=Myasthenia Gravis Activities of Daily Living

#### SELECT IMPORTANT SAFETY INFORMATION

Before taking VYVGART or VYVGART HYTRULO, tell your doctor if you: take any medicines, including prescription and non-prescription medicines, supplements, or herbal medicines; have received or are scheduled to receive a vaccine (immunization); or have any allergies or medical conditions, including if you are pregnant or planning to become pregnant, or are breastfeeding.



**VÝVGART**<sup>®</sup>**Hytrulo** 

(efgartigimod alfa and

hyaluronidase-qvfc)

(efgartigimod

Injection for Intravenous Use

400 mg/20 mL via**l** 

Take a moment to get your MG-ADL symptom score using the interactive tool at GetYourSymptomScore.com or the worksheet on the next page. Is this current level of symptom control acceptable to you?



1

2

Is there something you would get back to doing if your gMG symptoms and your daily abilities could be improved? You can use this space to write down anything else you'd like to talk to your doctor about, including your goals for your treatment plan.



Could VYVGART be right for you? Learn more at VYVGART.com

#### SELECT IMPORTANT SAFETY INFORMATION

The most common side effects in efgartigimod-alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. Additional common side effects with VYVGART HYTRULO are injection site reactions, including rash, redness of the skin, itching sensation, bruising, pain, and hives. These are not all the possible side effects of VYVGART and VYVGART HYTRULO. 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.

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



### Your anti-AChR antibody positive gMG symptoms

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. 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.

Grade	0	1	2	3	<b>Score</b> (0, 1, 2, or 3)
1. Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal, but can be understood	Difficult to understand speech	<b>_</b>
2. Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube	, 
3. Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube	- -
4. Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence	- -
<b>5.</b> Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions	- -
<b>6.</b> Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance	
7. Double vision	None	Occurs, but not daily	Daily, but not constant	Constant	· 
8. Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant	Т

#### MG-ADL score total (Add lines 1-8) =

This information has been provided for educational purposes only and is not meant to be a substitute for professional medical advice. Patients should not use this information for diagnosing a health condition. Patients should always consult a healthcare professional for medical advice or information about diagnosis and treatment. **Source:** Wolfe GI, et al. Neurology. 1999;52(7):1487-1489.





## Your daily abilities

You can use the space below to describe your anti-AChR antibody positive gMG symptoms and how they impact your daily abilities

<b>1.</b> Talking	
2. Chewing	
<b>3.</b> Swallowing	
4. Breathing	
<b>5.</b> Impairment of ability to brush teeth or comb hair	
<b>6.</b> Impairment of ability to arise from a chair	
7. Double vision	
8. Eyelid droop	

In addition to the severity of your anti-AChR antibody positive gMG symptoms and how they impact your daily abilities, your neurologist may also ask you how frequently you experience each anti-AChR antibody positive gMG symptom.

# VYVGART may help you do more with your days

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



### VYVGART for IV infusion is proven to improve daily abilities and reduce muscle weakness

When added to their current gMG treatment, VYVGART for IV infusion helped patients in the study with anti-AChR antibody positive gMG achieve:

# Improved daily abilities

**68%** (44 of 65) of patients on VYVGART for IV infusion achieved a significant improvement in their ability to perform daily activities\*

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

# Reduced muscle weakness

**63%** (41 of 65) of patients on VYVGART for IV infusion achieved a significant reduction in muscle weakness<sup>†</sup>

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

VYVGART for IV infusion was evaluated in a global study of adults with anti-AChR antibody positive gMG.

The primary goals of the study were to examine effectiveness (improved daily abilities and reduced muscle weakness) and safety for FDA approval of VYVGART for IV infusion. The study examined the effectiveness and safety of VYVGART for IV infusion in 167 adults (18 years or older) with gMG. In addition to their current treatment, patients received either VYVGART for IV infusion or 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.

#### SELECT IMPORTANT SAFETY INFORMATION

VYVGART and VYVGART HYTRULO may increase the risk of infection. The most common infections for efgartigimod alfa-fcab-treated patients were urinary tract and respiratory tract infections. Signs or symptoms of an infection may include 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.





### VYVGART Hytrulo was found to be effective for adults with anti-AChR antibody positive gMG

The effectiveness of VYVGART Hytrulo was established through 2 studies.

In the VYVGART Hytrulo study, VYVGART Hytrulo for subcutaneous injection had a similar reduction in the harmful AChR antibodies that cause gMG symptoms as VYVGART for IV infusion.

In the VYVGART for IV infusion study, a reduction in harmful AChR antibodies was associated with improved daily abilities (reduction in total MG-ADL score).

See page 6 for study results.

**VYVGART Hytrulo study design:** The study compared antibody reduction in 110 adults (18 years or older) with gMG who remained on their current gMG treatment and were given either VYVGART Hytrulo for subcutaneous injection or VYVGART for IV infusion.



#### SELECT IMPORTANT SAFETY INFORMATION

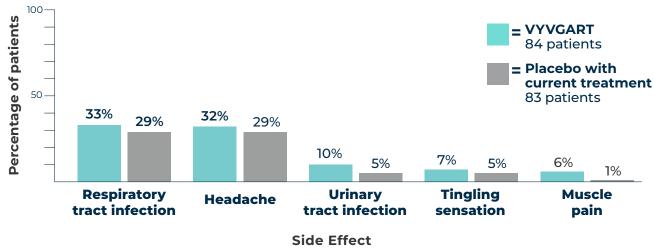
VYVGART and VYVGART HYTRULO can cause allergic reactions such as rashes, swelling under the skin, and shortness of breath. Hives were also observed in patients treated with VYVGART HYTRULO. Serious allergic reactions, such as trouble breathing and decrease in blood pressure leading to fainting have been reported with efgartigimod alfa-fcab.

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



### VYVGART for IV infusion has a proven safety profile

# In the study, the following side effects were reported in at least 5% of patients on VYVGART and more frequently than in patients on placebo with current treatment



Most infections in patients on VYVGART were mild to moderate. Additionally, more patients on VYVGART vs. placebo had lower white blood cell counts that were mild to moderate in severity.

VYVGART for IV infusion may increase the risk of allergic reactions including rash, swelling under the skin, and shortness of breath. It may also increase the risk of serious allergic reactions such as trouble breathing and decrease in blood pressure leading to fainting, as well as infusion-related reactions including increase in blood pressure, chills, shivering, and chest, abdominal, and back pain. These reactions can occur during or after treatment and can cause doctors to pause or, in some cases, stop treatment.

#### IV=intravenous



### VYVGART Hytrulo was safe in treating most patients studied

Comparable to the proven safety of VYVGART for IV infusion, although patients on VYVGART Hytrulo had more injection site reactions.

The overall safety of VYVGART Hytrulo for subcutaneous injection was consistent with the safety profile of VYVGART for IV infusion, except patients on VYVGART Hytrulo for subcutaneous injection experienced more injection site reactions.

In the VYVGART Hytrulo study, the most common side effects of VYVGART Hytrulo-treated patients were injection site reactions, 38% (21 of 55), and headache. Injection site reactions included injection site rash, redness of the skin, itching sensation, bruising, pain, and hives.

#### In the VYVGART Hytrulo study and its long-term safety study:

- All injection site reactions were mild to moderate and didn't lead to treatment discontinuation
- The majority of injection site reactions occurred within 24 hours of injection and resolved on their own
- The majority of injection site reactions occurred during the first treatment cycle and decreased with each subsequent cycle

#### Other side effects in the mild to moderate safety profile:

Some patients receiving VYVGART Hytrulo also experienced allergic reactions (hypersensitivity reactions). These included rash, swelling under the skin, shortness of breath, and hives. These reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation.

#### VYVGART Hytrulo may also:

- Increase the risk of serious allergic reactions, such as trouble breathing and decrease in blood pressure leading to fainting
- Increase the risk of infusion-related reactions, including increase in blood pressure, chills, shivering, and chest, abdominal, and back pain

These reactions can occur during or after treatment and can cause doctors to pause or, in some cases, stop treatment.

#### See more VYVGART study data at VYVGART.com



#### **IMPORTANT SAFETY INFORMATION**

Do not use VYVGART if you have a serious allergy to efgartigimod alfa or any of the other ingredients in VYVGART. Do not use VYVGART HYTRULO if you have a serious allergy to efgartigimod alfa, hyaluronidase, or any of the other ingredients in VYVGART HYTRULO. VYVGART and VYVGART HYTRULO can cause serious allergic reactions and a decrease in blood pressure leading to fainting.

# VYVGART and VYVGART HYTRULO may cause serious side effects, including:

- **Infection.** VYVGART and VYVGART HYTRULO may increase the risk of infection. The most common infections for efgartigimod alfa-fcab-treated patients were urinary tract and respiratory tract infections. Signs or symptoms of an infection may include 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.
- Allergic Reactions (hypersensitivity reactions). VYVGART and VYVGART HYTRULO can cause allergic reactions such as rashes, swelling under the skin, and shortness of breath. Hives were also observed in patients treated with VYVGART HYTRULO. Serious allergic reactions, such as trouble breathing and decrease in blood pressure leading to fainting have been reported with efgartigimod alfa-fcab.
- Infusion-Related Reactions. VYVGART and VYVGART HYTRULO can cause infusion-related reactions. The most frequent symptoms and signs reported with efgartigimod alfa-fcab were high blood pressure, chills, shivering, and chest, abdominal, and back pain.

Tell your doctor if you have signs or symptoms of an infection, allergic reaction, or infusion-related reaction. These can happen while you are receiving your VYVGART or VYVGART HYTRULO treatment or afterward. Your doctor may need to pause or stop your treatment. Contact your doctor immediately if you have signs or symptoms of a serious allergic reaction.

# Before taking VYVGART or VYVGART HYTRULO, tell your doctor if you:

- take any medicines, including prescription and non-prescription medicines, supplements, or herbal medicines,
- have received or are scheduled to receive a vaccine (immunization), or
- have any allergies or medical conditions, including if you are pregnant or planning to become pregnant, or are breastfeeding.

# What are the common side effects of VYVGART and VYVGART HYTRULO?

The most common side effects in efgartigimod-alfafcab-treated patients were respiratory tract infection, headache, and urinary tract infection. Additional common side effects with VYVGART HYTRULO are injection site reactions, including rash, redness of the skin, itching sensation, bruising, pain, and hives.

These are not all the possible side effects of VYVGART and VYVGART HYTRULO. 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.

#### What is VYVGART<sup>®</sup> (efgartigimod alfa-fcab) for intravenous (IV) infusion and what is VYVGART<sup>®</sup> HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection?

VYVGART and VYVGART HYTRULO are both prescription medicines, each 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).

Please see full Prescribing Information for <u>VYVGART for IV infusion</u> and <u>VYVGART HYTRULO</u> for subcutaneous injection, and talk to your doctor. VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) Subcutaneous Injection 180 mg/mL and 2000 U/mL vial



# VYVGART helps reduce harmful AChR antibodies, the main cause of gMG symptoms in people with anti-AChR antibody positive gMG

- VYVGART can improve daily abilities and reduce muscle weakness\*†
- VYVGART was **safe** in treating most patients studied
- VYVGART has a dosing plan **tailored specifically to you** and your response to treatment



#### Discover what's possible with VYVGART Hytrulo

Scan the QR code, visit **<u>HytruloForYou.com</u>**, or call **1-833-VYVGART (1-833-898-4278)** to learn more.

\*"Improved daily abilities" was defined as a decrease of 2 or more points on the MG-ADL scale. The improvement had to be maintained for 4 or more weeks, with the first improvement occurring within 1 week of the last injection of treatment cycle 1. The MG-ADL scale measures the severity of 8 common symptoms of gMG. A lower score means less severe symptoms.

+"Reduced muscle weakness" was defined as a decrease of 3 or more points on the Quantitative Myasthenia Gravis (QMG) scale. The improvement had to be maintained for 4 or more weeks, with the first improvement occurring within 1 week of the last injection of treatment cycle 1. The QMG scale assesses muscle weakness in gMG based on 13 items. A lower score means less muscle weakness.

AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; IV=intravenous; MG-ADL=Myasthenia Gravis Activities of Daily Living; QMG=Quantitative Myasthenia Gravis Visit <u>VYVGART.com/glossary</u> for a glossary of terms.

#### SELECT IMPORTANT SAFETY INFORMATION

VYVGART and VYVGART HYTRULO may increase the risk of infection. The most common infections for efgartigimod alfa-fcab-treated patients were urinary tract and respiratory tract infections. Signs or symptoms of an infection may include 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 full Prescribing Information for <u>VYVGART for IV infusion</u> and <u>VYVGART HYTRULO for subcutaneous injection</u>.

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