



VYVGART® for IV infusion and VYVGART Hytrulo® for SC injection

First and only IgG Fc-antibody fragment for the treatment of gMG in anti-AChR antibody-positive adults¹⁻³

Presented by Dr. Suraj Muley, MD, FAAN, FRCP, FACP

SELECT IMPORTANT SAFETY INFORMATION | CONTRAINDICATIONS

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

Please see Select Important Safety Information throughout and full prescribing information for both VYVGART and VYVGART Hytrulo available in this presentation.

AChR=acetylcholine receptor; Fc=fragment, crystallized; gMG=generalized myasthenia gravis; IgG=immunoglobulin G; IV=intravenous; SC=subcutaneous.

References: 1. VYVGART®. Prescribing information. argenx US Inc; 2024. 2. Wolfe GI, et al. *J Neurol Sci*. 2021;430:118074.
VYVGART Hytrulo® (efgartigimod alfa and hyaluronidase-qvcf). Prescribing information. argenx US, Inc.; 2024.

VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvcf)
Subcutaneous injection
180 mg/mL and 2000 U/mL | 200 mg/mL and 2000 U/mL

VYVGART
(efgartigimod)
Intravenous
400 mg/2mL

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Indication for VYVGART® (efgartigimod alfa-fcab) for intravenous infusion and VYVGART Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection

VYVGART for intravenous (IV) infusion and VYVGART Hytrulo for subcutaneous (SC) injection are each indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.^{1,2}

Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART and VYVGART Hytrulo available in this presentation.

3

References: 1. VYVGART Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc). Prescribing information. argenx US, Inc.; 2024. 2. VYVGART® (efgartigimod alfa-fcab). Prescribing information. argenx US, Inc.; 2024.

VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)
Subcutaneous Injection
180 mg/mL and 2000 U/mL, 1 200 mg/mL, and 2000 U/mL

VYVGART®
(efgartigimod alfa-fcab)
Intravenous Injection
400 mg/2 mL vial

Select Important Safety Information

Contraindications

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

Please see Select Important Safety Information throughout this presentation.

Please see the full Prescribing Information for VYVGART and the full Prescribing Information for VYVGART Hytrulo available at this presentation.
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).

Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART and VYVGART Hytrulo available in this presentation.

VYVGART[®]
Hytrulo[®]
(efgartigimod alfa and hyaluronidase-qfc)

VYVGART[®]
(efgartigimod alfa-fc6)

Agenda



Overview of gMG



Targeting FcRn
with VYVGART



ADAPT and ADAPT-SC
Phase 3 clinical trial data



Dosing and administration

Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART and VYVGART Hytrulo available in this presentation.

FcRn=neonatal Fc receptor; gMG=generalized myasthenia gravis.

VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvfc)
Subcutaneous Injection
180 mg/mL and 2000 U/mL | 200 mg/mL and 2000 U/mL

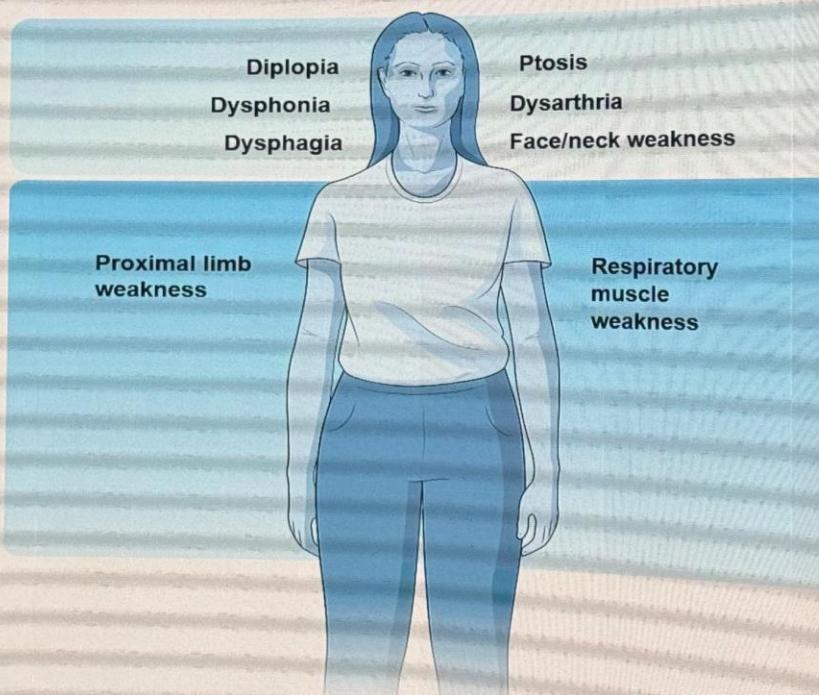
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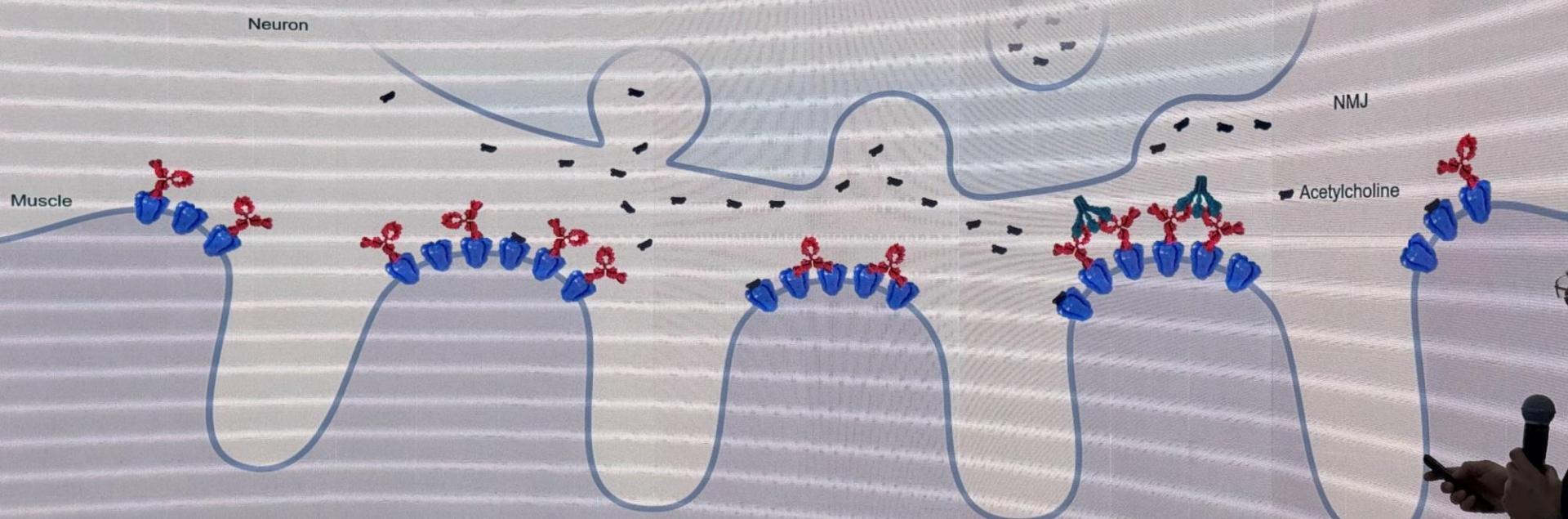
gMG: a chronic autoimmune disease that can cause debilitating muscle weakness^{1,2}

Common symptoms of gMG



Weakness typically **worsens with repetitive muscle use (fatigability)** and may vary over the course of a day, or from day to day

Approximately 85% of people with gMG have pathogenic IgG autoantibodies against AChR, which interrupt NMJ signaling¹⁻³

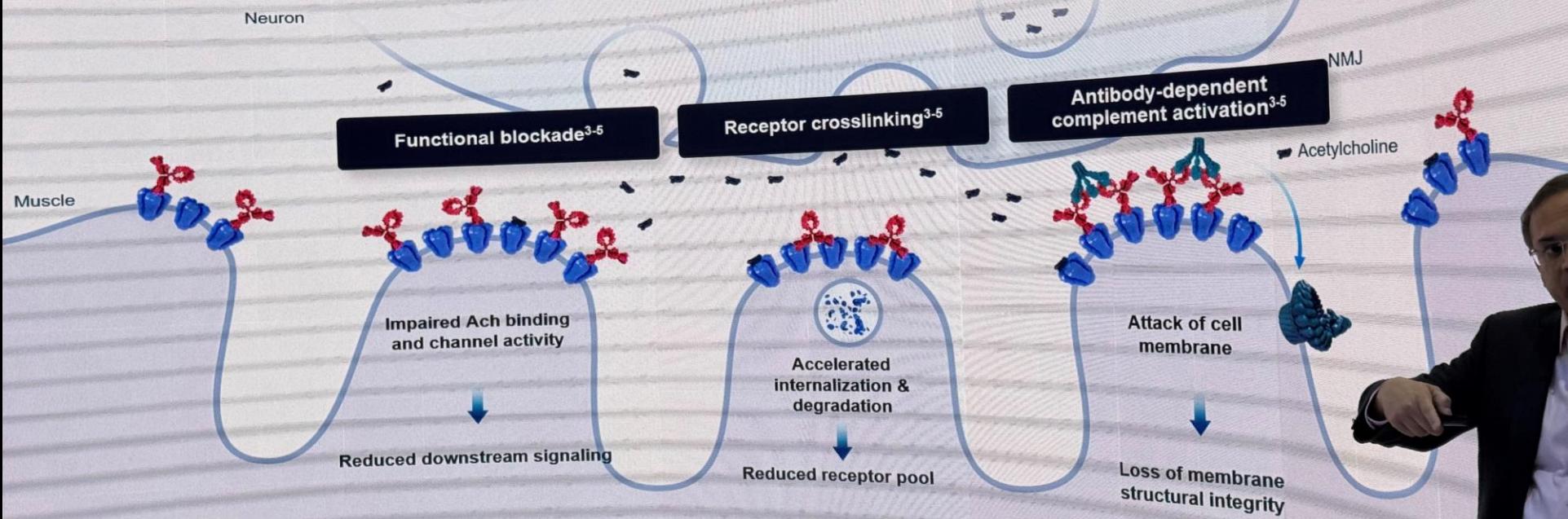


AChR=acetylcholine receptor; IgG=immunoglobulin G; NMJ=neuromuscular junction.

References: 1. Hehir MK, Silvestri NJ. *Neurol Clin.* 2018;36(2):253-260. 2. Gilhus NE, et al. *Nat Rev Neurol.* 2016;12(5):259-268. 3. Huijbers MG, et al. *J Intern Med.* 2014;275(1):12-26. 4. Mantegazza R, et al. *Neuropsychiatr Dis Treat.* 2011;7:151-160. 5. Koneczny I, Herbst R. *Cells.* 2019;8(7):671.



Approximately 85% of people with gMG have pathogenic IgG autoantibodies against AChR, which interrupt NMJ signaling¹⁻³



AChR=acetylcholine receptor; IgG=immunoglobulin G; NMJ=neuromuscular junction.

References: 1. Hehir MK, Silvestri NJ. *Neuro Clin*. 2018;36(2):253-260. 2. Gilhus NE, et al. *Nat Rev Neurol*. 2016;12(5):259-268. 3. Huijbers MG, et al. *J Intern Med*. 2014;275(1):12-26. 4. Mantegazza R, et al. *Neuropsychiatr Dis Treat*. 2011;7:151-160. 5. Koneczny I, Herbst R. *Cells*. 2019;8(7):671.



People with gMG may experience a high symptom burden^{1,2}



Daily life

71% (N=1,299) have problems doing their usual activities^{1†}



Work

63% (N=150) have had career or education interruptions due to gMG symptoms^{2‡}



Independence

60% (N=1,177) report that they've lost some personal independence^{1†§}

62%

of patients who were taking a gMG medication (n=144) felt that their symptoms were significant enough to want to try an additional treatment^{2¶||}

¹Versus 23% (N=9,000) of the general population.¹

[†]Data for this comparative analysis is based on 2 multinational, observational studies conducted between 2020 and 2021. One study was conducted among patients with MG (N=2,074) and the other collected data from the general population (N=9,000). Patients with MG were at least 18 years of age with mild to severe MG.¹

²Data collected from an argenx-sponsored, cross-sectional study of 150 people who had a self-reported diagnosis of gMG from an HCP between June 22-30, 2020. Eligible patients were US residents who were ≥18 years old. The survey explored the gMG diagnosis process, burden of disease, and burden of treatment. QOL and disease burden were measured with the WHO-5 Well-Being Index and the MG-QOL15r.²

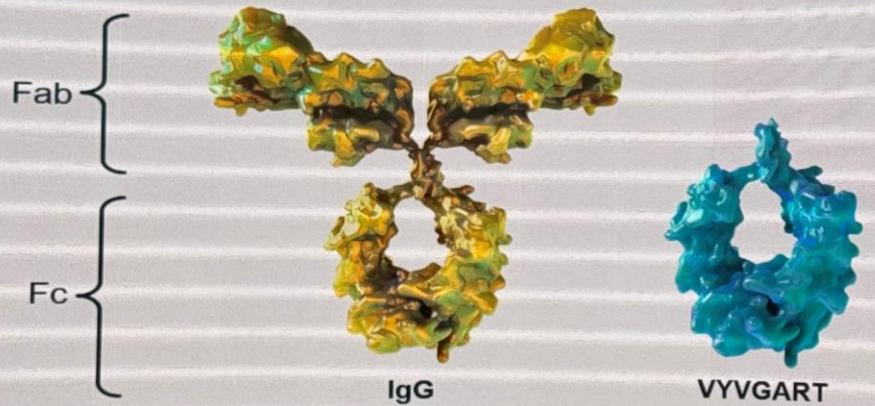
[†]Versus 16% (N=9,000) of the general population.¹

[‡]Traditional therapies included acetylcholinesterase inhibitors, corticosteroids, nonsteroidal immunosuppressants, and intravenous immunoglobulin.²

^{¶||}gMG=generalized myasthenia gravis; HCP=healthcare professional; MG=myasthenia gravis; MG-QOL15r=Revised Myasthenia Gravis Quality of Life; QOL=quality of life; US=United States; WHO=World Health Organization.

[§]References: 1. Dewilde S, et al. *Adv Ther*. 2023;41:271-291. 2. Muley S, et al. Presented at: 43rd Annual Carrell-Krusen Neuromuscular Symposium; February 18-19, 2021; USA (Virtual).

VYVGART, also known as efgartigimod alfa, is the first and only IgG Fc-antibody fragment for the treatment of gMG in adult patients who are anti-AChR antibody positive¹⁻³



VYVGART is the Fc portion of an IgG antibody*, engineered for affinity to FcRn¹

VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) is a coformulation of efgartigimod alfa (the same active ingredient in **VYVGART** for intravenous infusion) and hyaluronidase engineered for subcutaneous injection^{4†}

VYVGART targets and blocks FcRn to decrease IgG antibodies, including AChR autoantibodies, resulting in a decrease of pathogenic activity at the NMJ²

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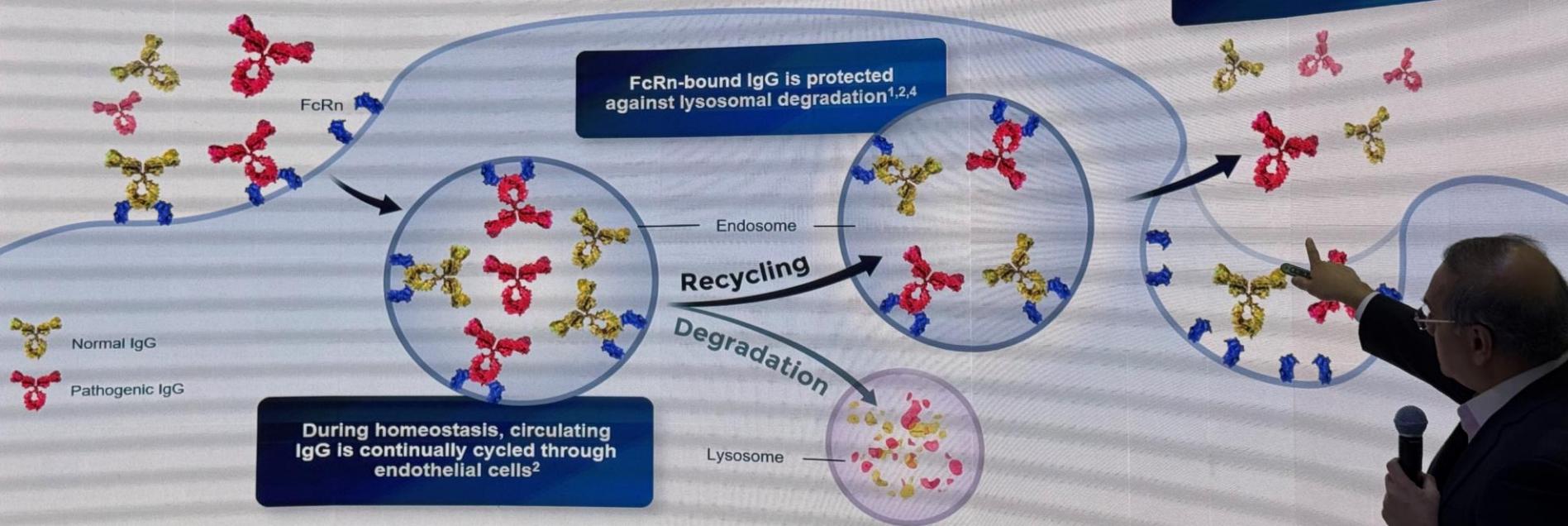
*Human IgG-derived.¹

¹Hyaluronidase depolymerizes hyaluronan, increasing the permeability of subcutaneous tissue.⁴

AChR=acetylcholine receptor; Fab=fragment, antigen-binding; FcRn=neonatal Fc receptor; Fc=fragment, crystallized; gMG=generalized myasthenia gravis; IgG=immunoglobulin G; NMJ=neuromuscular junction...

References: 1. VYVGART® (efgartigimod alfa-fcab). Prescribing information. argenx US, Inc.; Updated December 17, 2021. Accessed January 6, 2025. <https://clinicaltrials.gov/ct2/show/NCT03669588>. 2. Wolfe GI, et al. J Neurol Sci. 2021;430:118074. 3. FDA. FDA Approves New Treatment for Myasthenia Gravis. 2024.

FcRn plays a key role in gMG by recycling harmful IgG antibodies¹⁻⁴

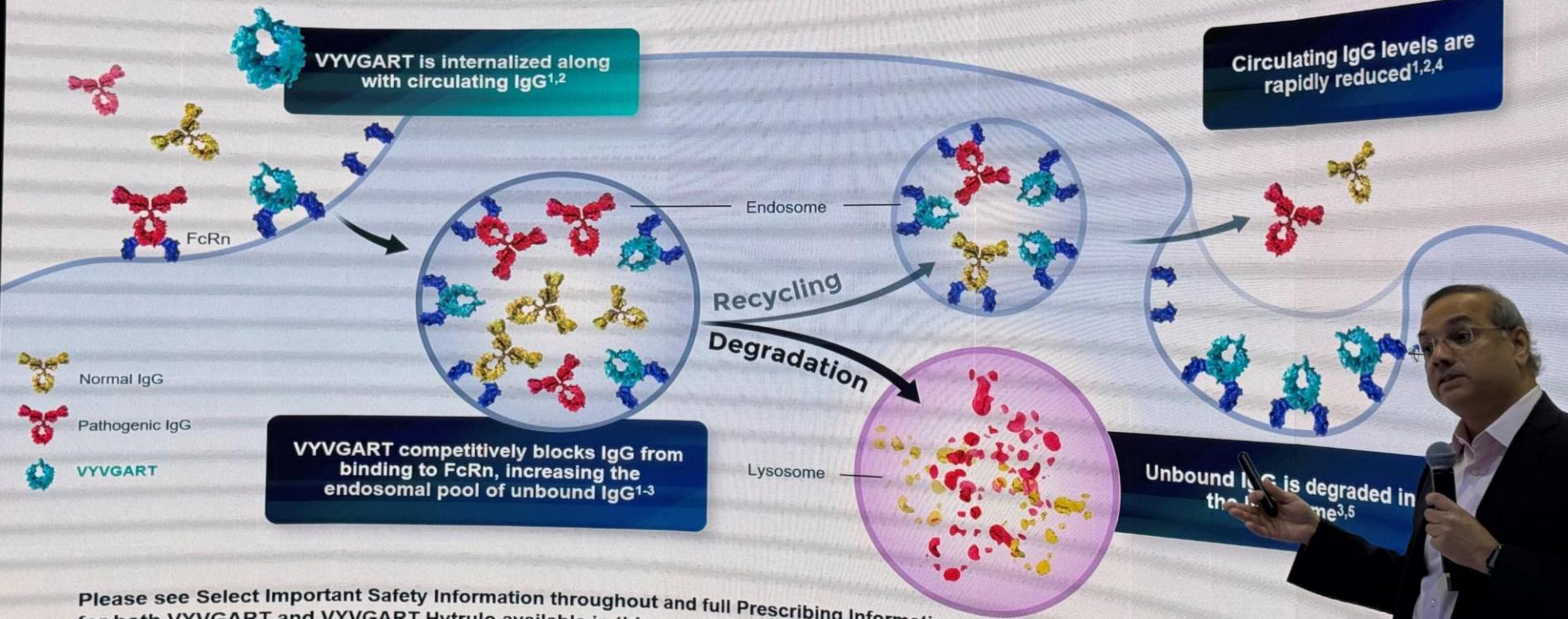


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Fc=fragment, crystallized; FcRn=neonatal Fc receptor; IgG=immunoglobulin G.

References: 1. Roopenian DC, Akilesh S. *Nat Rev Immunol*. 2007;7(9):715-725. 2. Ward ES, Ober RJ. *Trends Pharmacol Sci*. 2018;39(10):892-904. Gillius NE, et al. *Nat Rev Neurol*. 2016;12(5):259-268. 4. Wolfe GI, et al. *J Neurol Sci*. 2021;430:118074.

VYVGART targets and blocks FcRn, helping reduce circulating IgG¹⁻⁴



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Fc=fragment, crystallized; FcRn=neonatal Fc receptor; IgG=immunoglobulin G.

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Select Important Safety Information

Warnings and precautions | Infection

VYVGART and VYVGART HYTRULO may increase the risk of infection. The most common infections observed in Study 1 were urinary tract infection (10% of efgartigimod alfa-fcab-treated patients vs 5% of placebo-treated patients) and respiratory tract infection (33% of efgartigimod alfa-fcab-treated patients vs 29% of placebo-treated patients). Patients on efgartigimod alfa-cab vs placebo had below normal levels for white blood cell counts (12% vs 5%, respectively), lymphocyte counts (28% vs 19%, respectively), and neutrophil counts (13% vs 6%, respectively). The majority of infections and hematologic abnormalities were mild to moderate in severity. Delay the administration of VYVGART or VYVGART HYTRULO in patients with an active infection until the infection has resolved; monitor for clinical signs and symptoms of infections. If serious infection occurs, administer HYTRULO until the infection has resolved.

Please see Select Important Safety Information throughout this presentation.

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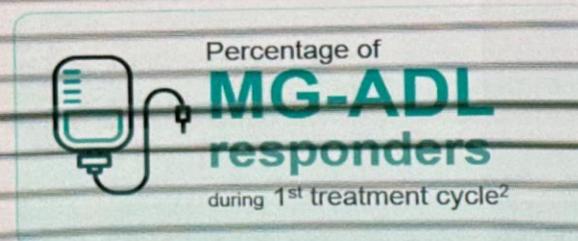
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Overview of trials being discussed today

ADAPT

Pivotal Phase 3 study to assess the safety and efficacy of **VYVGART** for IV infusion vs placebo^{1,2}

Primary endpoint



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IgG=immunoglobulin G; IV=intravenous; MG-ADL=Myasthenia Gravis Activities of Daily Living; SC, subcutaneous

References: 1. VYVGART® (elgartigimod alfa-fcab). Prescribing information. argenx US, Inc.; 2024. 2. Howard JF Jr, et al. *Lancet Neurol*. 2021;20(7):526-536. VYVGART Hytrulo® (elgartigimod alfa and hyaluronidase-qvc). Prescribing information. argenx US, Inc.; 2024. 4. Howard JF Jr, et al. *Neurother*. 2024;21:e00378.

15

ADAPT-SC

Bridging Phase 3, non-inferiority study to compare the pharmacodynamic (PD) effects of **VYVGART Hytrulo** for SC injection and **VYVGART** for IV infusion^{1,3,4}

Primary endpoint



Select Important Safety Information

Warnings and precautions Infusion-related reactions

Infusion-related reactions have been reported with intravenous efgartigimod alfa-fcab in postmarketing experience. The most frequent symptoms and signs were hypertension, chills, shivering, and thoracic, abdominal, and back pain. Infusion-related reactions occurred during or within an hour of administration and led to infusion discontinuation. If a severe infusion-related reaction occurs during administration, discontinue VYVGART infusion and initiate appropriate therapy. If a severe infusion-related reaction occurs with VYVGART HYTRULO, initiate appropriate therapy. Consider the risks and benefits of readministering VYVGART or VYVGART HYTRULO following a severe infusion-related reaction. If a mild to moderate infusion-related reaction occurs, patients may be rechallenged with close clinical observation, slower infusion rates, and pre-medications.

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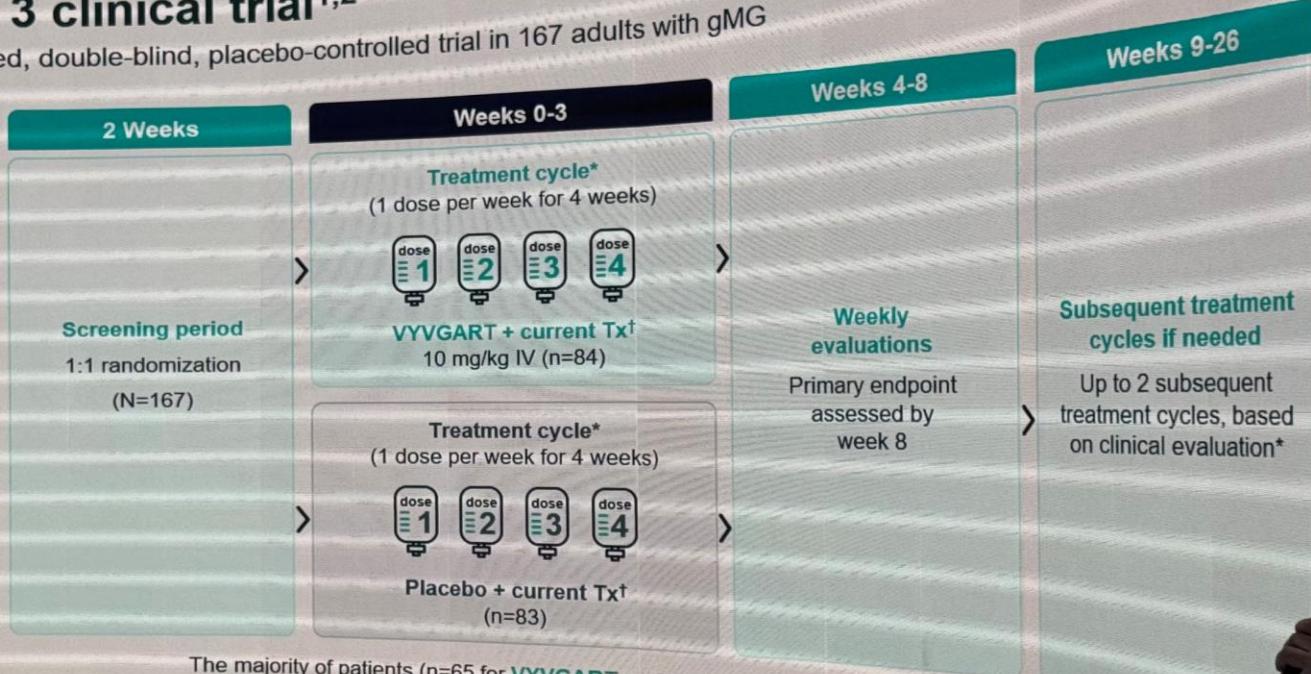


The ADAPT Phase 3 clinical trial^{1,2}

A 26-week, multicenter, randomized, double-blind, placebo-controlled trial in 167 adults with gMG

Primary endpoint

Percentage of anti-AChR antibody-positive patients who were MG-ADL responders, defined as a ≥2-point reduction in total MG-ADL score versus baseline for ≥4 consecutive weeks during the 1st treatment cycle (by Week 8), with first reduction occurring ≤1 week after last infusion of the cycle



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*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 non-ocular) and if the patient was an MG-ADL responder when they no longer had a clinically meaningful decrease (defined as having ≥2-point improvement in total MG-ADL score) compared to baseline. The minimum time between treatment cycles, specified by the study protocol, was 4 weeks from the last infusion. A maximum of 3 cycles were possible in the 26-week study.²

¹All patients received stable doses of their current gMG treatment.²

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

References: 1. VYVGART® (efgartigimod alfa-icab). Prescribing information. argenx US, Inc.; 2024. 2. Howard JF Jr, et al. *Lancet Neurol*. 2021;20(7):526-536.

7

VYVGART Hytrulo®
(efgartigimod alfa and hyaluronidase-qvcf)
Subcutaneous injection
100 mg/0.5 mL and 2000 mg/2 mL and 20000 mg/20 mL vials

VYVGART®
(efgartigimod alfa-icab)
Intravenous injection
400 mg/20 mL vial

Baseline characteristics in ADAPT were similar between treatment groups¹⁻³

	VYVGART (n=84)	PLACEBO (n=83)	VYVGART (n=84)	PLACEBO (n=83)
Demographics				
Age, mean, years (SD)	45.9 (14.4)	48.2 (15.0)		
Female, n (%)	63 (75)	55 (66)		
AChR antibody positive, n (%)	65 (77)	64 (77)		
Time since diagnosis, mean, years (SD)	10.1 (9.0)	8.8 (7.6)		
Functional scores				
MG-ADL score, mean (SD)	9.2 (2.6)	8.8 (2.3)		
MG-ADL 5-7, %	24	27		
MG-ADL 8-9, %	37	41		
MG-ADL ≥10, %	39	33		
QMG score, mean (SD)	16.2 (5.0)	15.5 (4.6)		
MGFA class at screening, n (%)				
Class II	34 (40)	31 (37)		
Class III	47 (56)	49 (59)		
Class IV	3 (4)	3 (4)		
Prior treatment				
Previous thymectomy, n (%)			59 (70)	36 (43)
No prior treatment with NSIST, n (%)			22 (26)	26 (31)
MG therapies at baseline, n (%)			60 (71)	67 (81)
Any steroid			51 (61)	51 (61)
Any NSIST*			>80	>80
AChE inhibitors, %				

5 most prevalent comorbidities at baseline (overall population)

- Hypertension: 28%
- Depression: 13%
- Diabetes Mellitus: 10%
- Osteoporosis: 9%
- Gastroesophageal Reflux Disease: 9%

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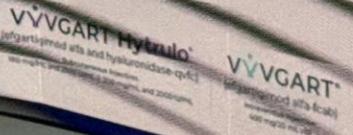
*Including azathioprine, cyclosporine, cyclophosphamide, methotrexate, mycophenolate mofetil, and tacrolimus (as monotherapy or in combination therapy).⁴

AChe = Acetylcholinesterase; AChR = acetylcholine receptor; MG = myasthenia gravis; MG-ADL = Myasthenia Gravis Activities of Daily Living; MGFA = Myasthenia Gravis Foundation of America; NSIST = nonsteroidal

immunosuppressive therapy; QMG = Quantitative Myasthenia Gravis; SD = standard deviation.

References: 1. Howard JF Jr, et al. *Lancet Neurol*. 2021;20(7):526-536. 2. Data on file. REF-00690: argenx US, Inc., 2021. 3. Data on file. REF-00692: argenx US, Inc., 2021.

Lascacio AM, et al. *Autoimmun Rev*. 2021;20(1):102712.

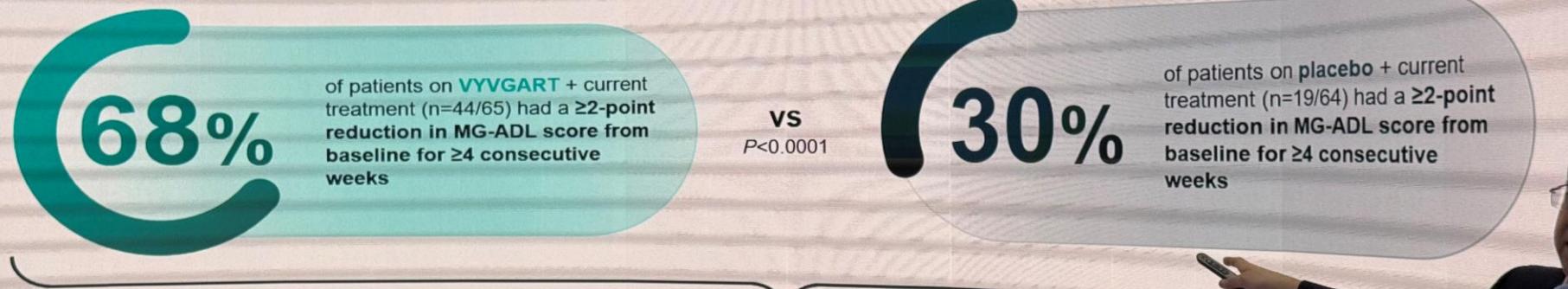




Significant, sustained improvement for ≥4 weeks in daily function in patients treated with VYVGART versus placebo^{1,2*}

Primary endpoint

Observed during 1st treatment cycle:



>2x as many patients

treated with **VYVGART** had improved daily function sustained for ≥4 weeks during the 1st treatment cycle

Please see Select Important Safety Information throughout and full Prescribing Information for both **VYVGART** and **VYVGART Hytrulo** available in this presentation.

*The primary endpoint was the percentage of patients who were anti-AChR antibody-positive and were MG-ADL responders, 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 during the 1st treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.^{1,2}

AChR=acetylcholine receptor; MG-ADL=Myasthenia Gravis Activities of Daily Living.

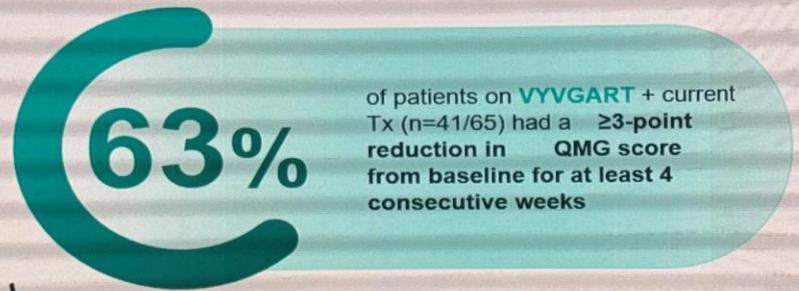
References: 1. VYVGART® (efgartigimod alfa-icab). Prescribing information. argenx US, Inc.; 2024. 2. Howard JF Jr, et al. *Lancet Neurol*. 2021;20(7):526-536.

VYVGART Hytrulo
efgartigimod alfa and hyaluronidase-
Qb
Subcutaneous injection
100 mg/mL and 2000 U/mL, 1,000 mg/mL, and 2000 mg/mL
efgartigimod alfa
hyaluronic acid
400 mg/mL

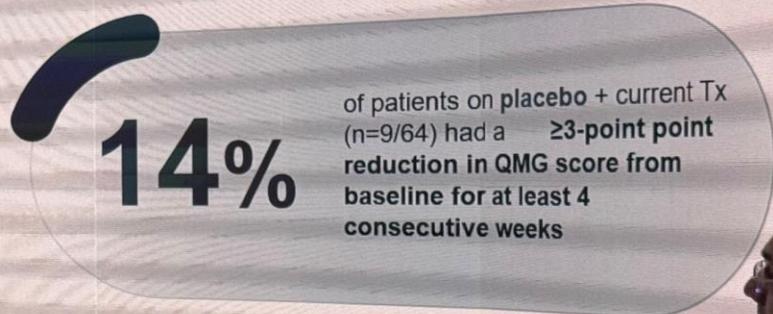
Significant, sustained reduction for ≥4 weeks in muscle weakness in patients treated with VYVGART versus placebo^{1,2}

Secondary endpoint*

Observed during 1st treatment cycle:



VS
P<0.0001



>4x as many patients

treated with VYVGART had a reduction in muscle weakness sustained for ≥4 weeks during the 1st treatment cycle

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*The secondary endpoint was the percentage of patients who were anti-AChR antibody-positive and QMG responders, defined as patients with a ≥3-point reduction in the total QMG score compared to the treatment cycle baseline for at least 4 consecutive weeks during the 1st treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.¹
AChR=acetylcholine receptor; QMG=Quantitative Myasthenia Gravis; Tx=treatment.

References: 1. VYVGART® (efgartigimod alfa-fcab). Prescribing information. argenx US, Inc., 2024. 2. Howard JF Jr, et al. *Lancet Neurol*. 2021;20(7):526-536.

Select Important Safety Information

Warnings and precautions | Immunization

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

Please see Select Important Safety Information throughout this presentation.

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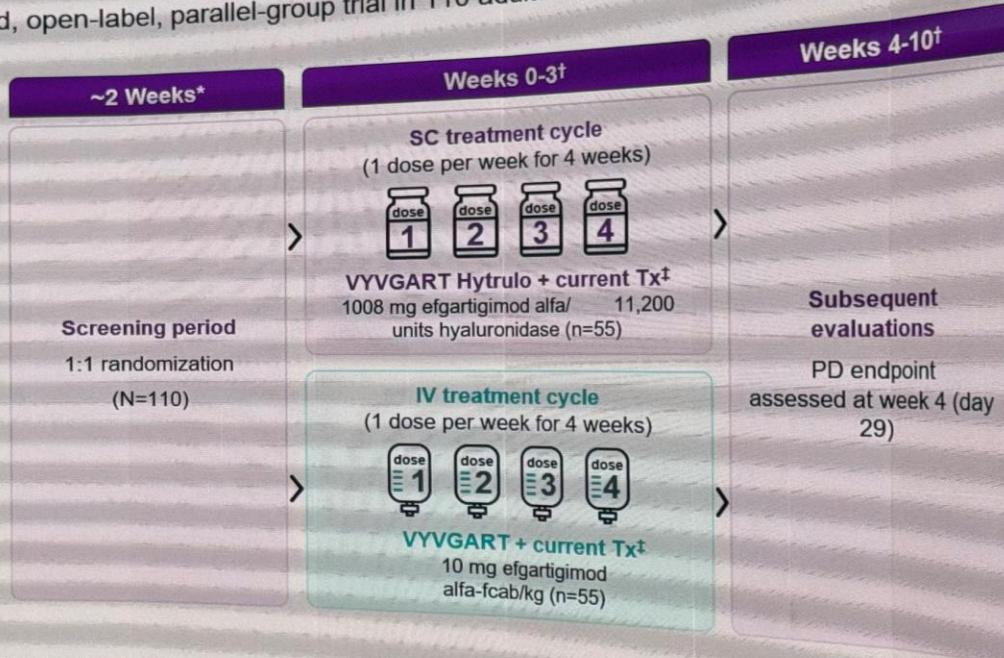
The ADAPT-SC Phase 3 clinical trial^{1,2}

A 10-week, phase 3, multicenter, randomized, open-label, parallel-group trial in 110 adults with gMG

PD endpoint

The pharmacological effect of **VYVGART Hytrulo** administered SC was compared to **VYVGART** administered IV in adult patients with gMG

- Efficacy of **VYVGART Hytrulo** is based on this PD bridging study, which assessed the decrease in AChR-autoantibody levels
- The majority of patients (n=91) were positive for AChR antibodies
- In addition to pharmacodynamics, safety of **VYVGART Hytrulo** was also assessed
- Eligible patients were able to enter the open-label extension of ADAPT-SC+ trial



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*MG-ADL total score of ≥5 required at screening with >50% of the total.¹

[†]Patients were evaluated weekly from weeks 1-8, and then at week 10.¹

[‡]All patients received stable doses of their current gMG Tx.¹

AChR=acetylcholine receptor; gMG=generalized myasthenia gravis; MG-ADL=Myasthenia Gravis Activities of Daily Living; IV=intravenous; PD=pharmacodynamic; SC=subcutaneous; Tx=treatment.
1. Howard JF Jr, et al. Neurother. 2024;21:e00378. 2. VYVGART Hytrulo® (efgartigimod alfa and hyaluronidase-qvc). Prescribing information. argenx US, Inc.; 2024.

Baseline characteristics were similar between treatment groups^{1,2}

	VYVGART Hytrulo (n=55)	VYVGART (n=55)	VYVGART Hytrulo (n=55)	VYVGART (n=55)
Demographics				
Age, mean, years (SD)	50.9 (15.8)	55.8 (15.4)	16 (29.1)	13 (23.6)
Female, n (%)	31 (56.4)	34 (61.8)	MG therapies at baseline, n (%)	40 (72.7)
Anti-AChR antibody positive, n (%)	45 (81.8)	46 (83.6)	Any steroid	33 (60.0)
Time since diagnosis, mean, years (SD)	6.3 (6.4)	7.7 (8.5)	Any NSIST*	23 (41.8)
Functional scores				
MG-ADL score, mean (SD)	8.8 (2.6)	8.5 (2.6)	Any AChE inhibitor	25 (45.5)
MG-ADL 5-7, %	36	44	48 (87.3)	47 (85.5)
MG-ADL 8-9, %	29	22		
MG-ADL ≥10, %	35	35		
QMG score, mean (SD)	14.9 (4.4)	15.5 (4.5)		
MGFA class at screening, n (%)				
Class II	29 (52.7)	22 (40.0)		
Class III	24 (43.7)	30 (54.5)		
Class IV	2 (3.6)	3 (5.5)		

Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART and VYVGART Hytrulo available in this presentation.

*Including azathioprine, cyclosporine, cyclophosphamide, methotrexate, mycophenolate mofetil, and tacrolimus (as monotherapy or in combination therapy).¹
 AChE=acetylcholinesterase; AChR=acetylcholine receptor; MG=myasthenia gravis; MG-ADL=Myasthenia Gravis Activities of Daily Living; MGFA=Myasthenia Gravis Foundation of America; NSIST=nonsteroidal immunosuppressive therapy; QMG=Quantitative Myasthenia Gravis; SD=standard deviation.
 Reference: 1. Howard JF Jr, et al. Neurother. 2024;21:e00378. 2. Data on file. REF-01893. argenx US, Inc.; 2023.

Select Important Safety Information

Warnings and precautions Hypersensitivity reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART or VYVGART HYTRULO. Urticaria was also observed in patients treated with VYVGART HYTRULO. Hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation. Anaphylaxis and hypotension leading to syncope have been reported in postmarketing experience with intravenous efgartigimod alfa-fcab. Anaphylaxis and hypotension occurred during or within an hour of administration and led to infusion discontinuation and in some cases to permanent treatment discontinuation. Healthcare professionals should monitor patients during and for 1 hour after VYVGART administration, or for at least 30 minutes after VYVGART HYTRULO administration, for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs, the healthcare professional should institute appropriate measures if needed or the patient should seek medical attention.

Please see Select Important Safety Information throughout this presentation.

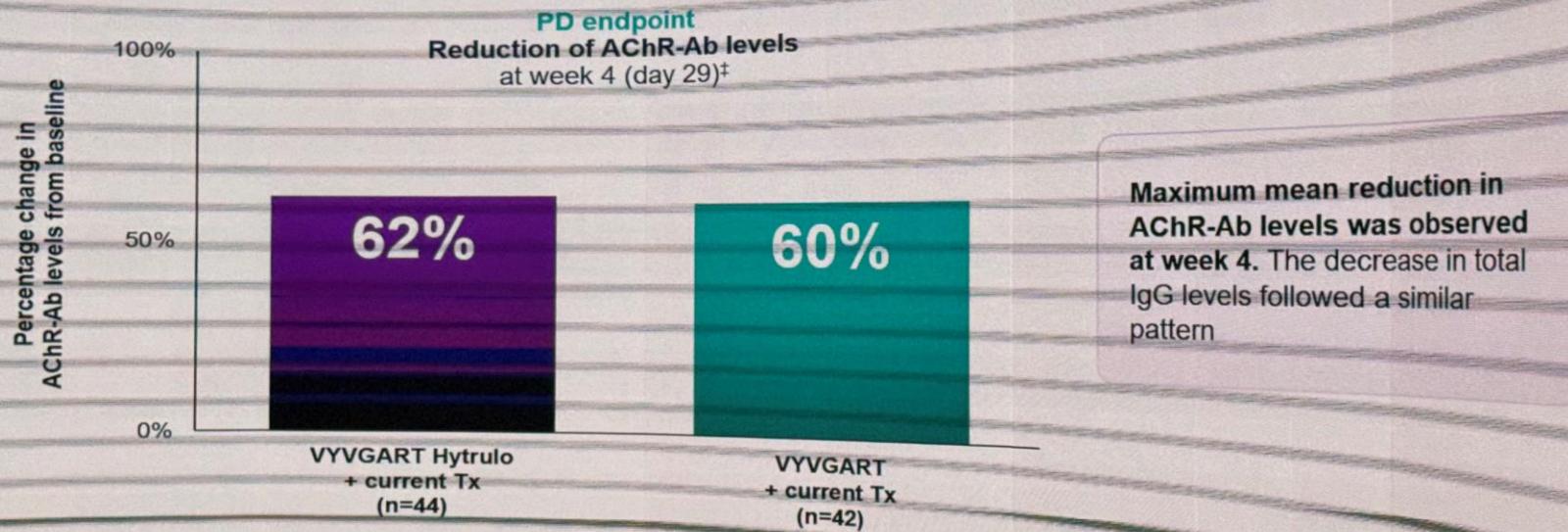
Please see the full Prescribing Information for VYVGART Hytrulo and the full Prescribing Information for VYVGART available at this presentation.

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).

Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART and VYVGART Hytrulo available in this presentation.



VYVGART Hytrulo had a comparable PD effect to VYVGART in reduction of AChR-Ab levels at week 4^{1,2*†}



Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART and VYVGART Hytrulo available in this presentation.

*The 90% confidence interval for the geometric mean ratios of AChR-Ab reduction at day 29 and AUEC_{0-4w} were within the range of 80% to 125%, indicating no clinically significant difference between the two formulations.[†]

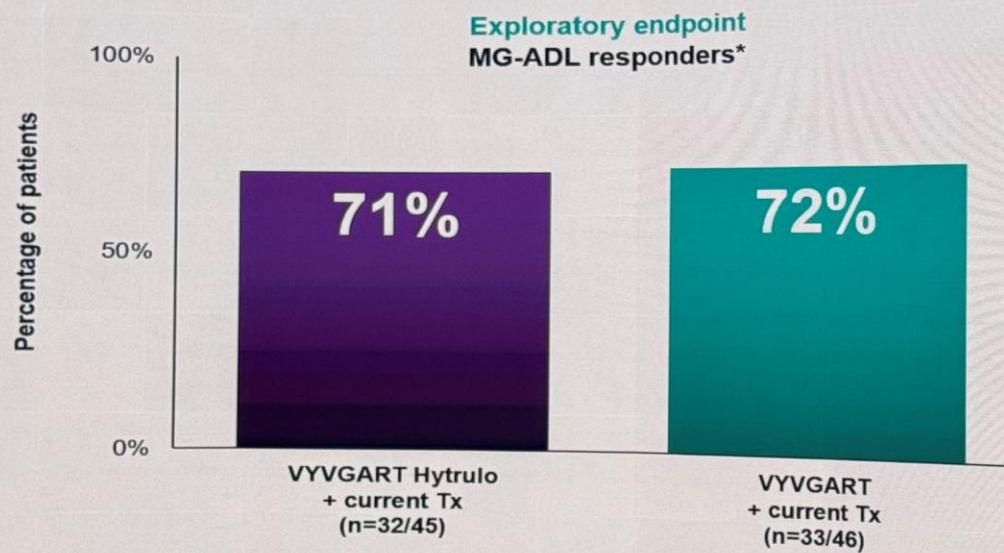
[‡]Clinical trial data for patients who are anti-AChR antibody-positive.¹

[†]Seven days after the fourth IV or SC administration.¹

AChR-Ab = acetylcholine receptor antibody; AUEC_{0-4w} = area under the effect-time curve from time 0 to 4 weeks post-dose; IgG = immunoglobulin G; IV = intravenous; PD = pharmacodynamic; SC = subcutaneous; Tx = treatment.

References: 1. VYVGART Hytrulo® (efgartigimod alfa and hyaluronidase-qfc). Prescribing Information. argenx US, Inc.; 2024. 2. Data on file. REF-01900. argenx US, Inc., 2023.

MG-ADL response data for VYVGART Hytrulo and VYVGART



MG-ADL response defined as a ≥2-point reduction in the total MG-ADL score compared to the treatment cycle baseline for ≥4 consecutive weeks during the study period, with the first reduction occurring no later than 1 week after the last injection of the cycle

Limitations: ADAPT-SC was a bridging study designed to compare PD effects between VYVGART Hytrulo for SC injection and VYVGART for IV infusion. MG-ADL response in the AChR-antibody positive subgroup was observed for exploratory purposes; therefore, data should be interpreted with caution and conclusions cannot be drawn.

Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART and VYVGART Hytrulo available in this presentation.

*Clinical trial data from patients who were anti-AChR antibody-positive.

AChR=acetylcholine receptor; IV=intravenous; MG-ADL=Myasthenia Gravis Activities of Daily Living; PD=pharmacodynamic; SC=subcutaneous; TX=treatment.



VYVGART Hytrulo[®]
(efgartigimod alfa and hyaluronic acid-qfc)
160 mg/kg, and 2000 units, 1 200 mg/kg, and 2000 units.

VYVGART[®]
(efgartigimod alfa)

VYVGART had a demonstrated safety profile in the ADAPT clinical trial

Adverse reactions in
≥5% of patients
 treated with **VYVGART** and more frequently than placebo in ADAPT

	VYVGART (n=84)	PLACEBO (n=83)
Adverse reaction		
Respiratory tract infection	33%	29%
Headache*	32%	29%
Urinary tract infection	10%	5%
Paresthesia†	7%	5%
Myalgia	6%	1%

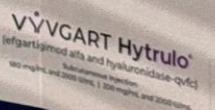
- A higher frequency of patients who received **VYVGART** compared with placebo were observed to have below-normal levels for **white blood cell counts** (12% vs 5%), **lymphocyte counts** (28% vs 19%), and **neutrophil counts** (13% vs 6%)
- The majority of infections and hematologic abnormalities were **mild to moderate** in severity
- In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in **VYVGART**-treated patients. Hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation
- Postmarketing experience with **VYVGART** included reports of anaphylaxis and hypotension leading to syncope, as well as infusion-related reactions including hypertension, chills, shivering, and thoracic, abdominal, and back pain. These reactions occurred during or within an hour of administration and led to infusion discontinuation and, in some cases, to permanent treatment discontinuation

Please see Select Important Safety Information throughout and full Prescribing Information for both **VYVGART** and **VYVGART Hytrulo** available in this presentation.

*Headache includes migraine and procedural headache.

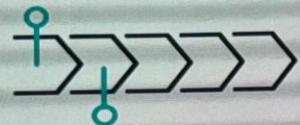
†Paresthesia includes oral hypoesthesia, hypoesthesia, and hyperesthesia.

Reference: VYVGART® (efgartigimod alfa-fcab). Prescribing Information. argenx US, Inc.; 2024.



Except for higher rate of injection site reactions (ISRs), overall safety profile for VYVGART Hytrulo consistent with proven safety profile of VYVGART^{1,2}

38% of patients receiving VYVGART Hytrulo (n=55) in ADAPT-SC had ISRs (rash, erythema, pruritus, bruising, pain, and urticaria).¹ In ADAPT-SC and its open-label extension (n=168), ISRs:¹



were **mild to moderate** in severity and did not lead to treatment discontinuation.^{1,2}



primarily occurred within 24 hours after administration and resolved spontaneously.¹



primarily occurred during 1st treatment cycle, with decreasing incidence for subsequent cycles.^{1,2*}

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART Hytrulo or VYVGART. Urticaria was also observed in patients treated with VYVGART Hytrulo. Hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation.^{1,3}

Postmarketing experience with VYVGART included reports of anaphylaxis and hypotension leading to syncope, as well as infusion-related reactions including hypertension, chills, shivering, and thoracic, abdominal, and back pain. These reactions occurred during or within an hour of administration and led to infusion discontinuation and, in some cases, to permanent treatment discontinuation.¹

Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART and VYVGART Hytrulo available in this presentation.

*Cycle 1: 34.1% (n=56); cycle 2: 16.9% (n=24); cycle 3: 13.3% (n=14); and cycle 4: 11.8% (n=8). Interim results presented April 2023. The ADAPT-SC+ Open-Label Extension study is still ongoing.^{2,4}

ISR=Injection site reaction.

References: 1. VYVGART Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc). Prescribing information. argenx US, Inc.; 2024. 2. Howard JF Jr, et al. *Neurother*. 2024;21:e00378. 3. VYVGART® (efgartigimod alfa-fcab). Prescribing information. argenx US, Inc.; 2024. 4. Howard JF Jr, et al. Poster presented at: AAN Annual Meeting; April 22-27; Boston, MA.

VYVGART Hytrulo[®]
efgartigimod alfa and hyaluronidase-qvfc
100 mg/mL and 3000 U/mL; 1, 200 mg/mL, and 2000 U/mL

VYVGART[®]
efgartigimod alfa-fcab
400 mg/mL

Select Important Safety Information

Warnings and precautions Adverse reactions

In Study 1, the most common ($\geq 10\%$) adverse reactions in efgartigimod alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. In Study 2, the most common ($\geq 10\%$) adverse reactions in VYVGART HYTRULO-treated patients were injection site reactions and headache. Injection site reactions occurred in 38% of VYVGART HYTRULO-treated patients, including injection site rash, erythema, pruritus, bruising, pain, and urticaria. In Study 2 and its open-label extension, all injection site reactions were mild to moderate in severity and did not lead to treatment discontinuation. The majority occurred within 24 hours after administration and resolved spontaneously. Most injection site reactions occurred during the 1st treatment cycle, and the incidence decreased with each subsequent cycle.

Please see Select Important Safety Information throughout this presentation.

Please see the full Prescribing Information for VYVGART and the full Prescribing Information for VYVGART Hytrulo available at this presentation.
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).

Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART and VYVGART Hytrulo available in this presentation.

Two routes of administration that may help meet your patients' dosing needs

Recommended dose and dosing schedules from Prescribing Information:

	VYVGART Hytrulo for SC injection ¹	VYVGART for IV infusion ²
Dosing	1,008 mg efgartigimod alfa/ 11,200 units hyaluronidase (fixed dose)	10 mg efgartigimod alfa-fcab/kg (weight based)*
Administration time	~30- to 90-second SC injection [†]	1-hour IV infusion
Observation time	30-minute observation	1-hour observation
Administration	HCP-administered	
Site of care	At an HCP's office, infusion center or outpatient hospital clinic, or at home with assistance from a nurse [‡]	
Frequency	One treatment cycle = once per week for 4 weeks Subsequent cycles based on clinical evaluation [§]	

The safety of initiating subsequent cycles sooner than 4 weeks from the last injection
or infusion of the previous treatment cycle has not been established^{1,2}

Please see Select Important Safety Information throughout and full Prescribing Information
for both VYVGART and VYVGART Hytrulo available in this presentation.

*In people weighing 265 lbs (120 kg) or more, the recommended dose of VYVGART is 1,200 mg (3 vials) per infusion.²

[†]Refers to the actual injection time of VYVGART Hytrulo. Allow for appropriate storage, preparation, and setup time before use.¹

[‡]Home infusions or injections may be available for patients with insurance coverage for this service. Please contact the patient's insurance provider directly.

[§]In the ADAPT phase 3 clinical trial, all patients received an initial cycle, with subsequent cycles administered according to individual clinical evaluation when their MG-ADL score was at least 5 (with >50% MG-ADL non-ocular) 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 the study protocol, was 4 weeks from the last infusion. A maximum of 3 cycles were possible in the 26-week study.³
HCP=healthcare provider; IV=intravenous; MG-ADL=Myasthenia Gravis Activities of Daily Living; SC=subcutaneous.

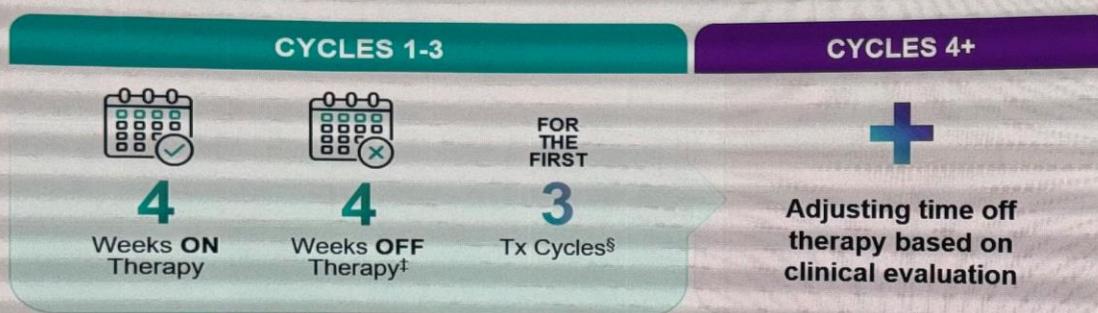
References: 1. VYVGART Hytrulo® (efgartigimod alfa and hyaluronidase-qfc). Prescribing information. argenx US, Inc.; 2024.

2. VYVGART® (efgartigimod alfa-fcab). Prescribing information. argenx US, Inc.; 2024. 3. Howard JF Jr, et al. *Lancet Neurol*. 2021;20(7):526-536.



VYVGART Hytrulo and VYVGART: an example approach to dosing

Based on the most commonly observed schedule from a post-hoc analysis of ADAPT-SC+ and ADAPT+^{1†}



For cycles 1 to 3, this example approach shows 4 weeks on and 4 weeks off therapy for 3 cycles

For subsequent cycles, continue evaluating the appropriate time off therapy based on clinical evaluation

Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART and VYVGART Hytrulo available in this presentation.

*ADAPT+ and ADAPT-SC+ were single-arm, open-label studies evaluating the long-term safety and tolerability of VYVGART and VYVGART Hytrulo.^{2,3}

[†]Analysis included all complete cycles, defined as cycles not interrupted by the cut-off/final study date of December 1, 2022, or a single incomplete cycle of at least 28 days.¹

[‡]Four weeks off starts after the last infusion of the most recent cycle.¹

[§]A cycle consists of 4 once-weekly doses over 22 days.¹

Tx=treatment.

References: 1. Data on file. REF-02349. argenx US, Inc.; 2023. 2. ClinicalTrials.gov. NCT03770403. Accessed December 12, 2023. <https://clinicaltrials.gov/study/NCT03770403>. 3. ClinicalTrials.gov. NCT04818671. Accessed December 12, 2023. <https://clinicaltrials.gov/study/NCT04818671>.

Limitations

The distributions of average cycle duration in ADAPT-SC+ and ADAPT+ were post-hoc descriptive analyses not controlled for multiplicity and not powered; therefore, data should be interpreted with caution and conclusions cannot be drawn.



VYVGART Hytrulo[®]
(ergartigimod alfa and hyaluronidase-qvc)
Biologics license application
100 mg/vial and 200 mg/vial, 1 200 mg/vial, and 2000 mg/vial

VYVGART[®]
(ergartigimod alfa-fcab)
Intravenous injection
400 mg/20 ml vial

Considerations for starting treatment^{1,2}

No treatment-specific vaccinations required to begin treatment

HCPs should evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with **VYVGART Hytrulo** or **VYVGART**.*



No REMS required

VYVGART Hytrulo and **VYVGART** do not require any specific training or certification prior to starting treatment at this time.



No routine laboratory monitoring required

No routine laboratory monitoring requirements for patients during treatment with **VYVGART Hytrulo** or **VYVGART**. Continue to evaluate response and monitor patients for possible side effects.[†]



No Boxed Warning

Please see the full Prescribing Information for **VYVGART Hytrulo** and **VYVGART** before starting patients on treatment.



Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART and VYVGART Hytrulo available in this presentation.

*In accordance with the recommendations found in Section 2.1 of the Prescribing Information.^{1,2}

[†]Patients in the ADAPT and ADAPT-SC clinical trials were required to have IgG levels of at least 6 g/L at study entry.^{1,2} Please also see the Warnings and Precautions found in Section 5 of the Prescribing Information. HCP=healthcare provider; IgG=immunoglobulin G; REMS=Risk Evaluation and Mitigation Strategy.

References: 1. VYVGART Hytrulo® (efgartigimod alfa and hyaluronidase-qvcf). Prescribing Information. argenx US, Inc.; 2024.

2. VYVGART™ (efgartigimod alfa-fcab). Prescribing Information. argenx US, Inc.; 2024.

VYVGART Hytrulo
(efgartigimod alfa and hyaluronidase-qvcf)
Subcutaneous Injection
100 mg/0.5 mL and 200 mg/1 mL, 100 mg/mL, and 200 mg/mL
100 mg/0.5 mL and 200 mg/1 mL, 100 mg/mL, and 200 mg/mL

VYVGART
(efgartigimod alfa-fcab)
Subcutaneous Injection
400 mg/20 mL vial

Considerations for starting treatment (cont'd)^{1,2}

MG-ADL assessments

Share the MG-ADL scale and work with patients to get their baseline score



Patient counseling information

Discuss the risk of infections, hypersensitivity reactions, and infusion-related reactions associated with their treatment*



Sites of care

Review options for administration to understand patient needs and preferences



Access to multiple treatment cycles

Initial authorization may allow for multiple treatment cycles for the majority of patients



Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART and VYVGART Hytrulo available in this presentation.

*Please also see the Patient Counseling Information in section 17 of the Prescribing Information.^{1,2}
MG-ADL=Myasthenia Gravis Activities of Daily Living.

References: 1. VYVGART Hytrulo® (efgartigimod alfa and hyaluronidase-qvc). Prescribing information. argenx US, Inc.; 2024.
2. VYVGART® (efgartigimod alfa-fcab). Prescribing information. argenx US, Inc.; 2024.

Select Important Safety Information

Use in specific populations

Pregnancy

As VYVGART and VYVGART HYTRULO are expected to reduce maternal IgG antibody levels, reduction in passive protection to the newborn is anticipated. Risk and benefits should be considered prior to administering live vaccines to infants exposed to VYVGART or VYVGART HYTRULO in utero.

Lactation

There is no information regarding the presence of efgartigimod alfa-fcab from administration of VYVGART, or efgartigimod alfa or hyaluronidase from administration of VYVGART HYTRULO, in human milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VYVGART or VYVGART HYTRULO, and any potential adverse effects on the breastfed infant from VYVGART or VYVGART HYTRULO or from the underlying maternal condition.

Please see Select Important Safety Information throughout this presentation.

Please see the full Prescribing Information for VYVGART and the full Prescribing Information for VYVGART Hytrulo available at this presentation.

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).

Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART and VYVGART Hytrulo available in this presentation.

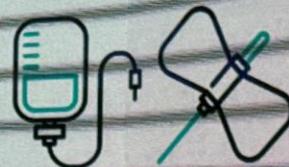
VYVGART Hytrulo and VYVGART can offer:^{1,2}



Significant response during the 1st treatment cycle*†



Demonstrated safety



Two routes of administration

In the ADAPT study, the most common ($\geq 10\%$) adverse reactions observed for efgartigimod alfa-fcab-treated patients vs placebo-treated patients were respiratory tract infection (33% vs 29%), headache (32% vs 29%), urinary tract infection (10% vs 5%), paresthesia (7% vs 5%), and myalgia (6% vs 1%).‡ In the ADAPT-SO study, common ($\geq 10\%$) adverse reactions with VYVGART Hytrulo-treated patients were injection site reactions (38%) and headache. In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea, were observed in patients treated with VYVGART Hytrulo or VYVGART Urticaria, observed in patients treated with VYVGART Hytrulo.

Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART and VYVGART Hytrulo available in this presentation.

*Patients were treated with VYVGART. †Current Tx or placebo + current Tx.^{1,2}

¹MG-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 1st treatment cycle (by week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.^{1,2}

²Adverse reactions in $\geq 5\%$ of participants treated with VYVGART and more frequently than placebo. Headache includes migraine and procedural headache. Paresthesia includes oral hypoesthesia, hypoesthesia, and hyperesthesia.

MG-ADL = Myasthenia Gravis Activities of Daily Living; Tx=treatment.

References: 1. VYVGART Hytrulo® (efgartigimod alfa and hyaluronidase-qvc). Prescribing information. argenx US, Inc., 2024.

2. VYVGART® (efgartigimod alfa-fcab). Prescribing information. argenx US, Inc., 2024.

VYVGART Hytrulo
efgartigimod alfa and hyaluronidase-qvc
100 mg/mL and 200 mg/mL | 100 mg/mL and 200 mg/mL

VYVGART
efgartigimod alfa