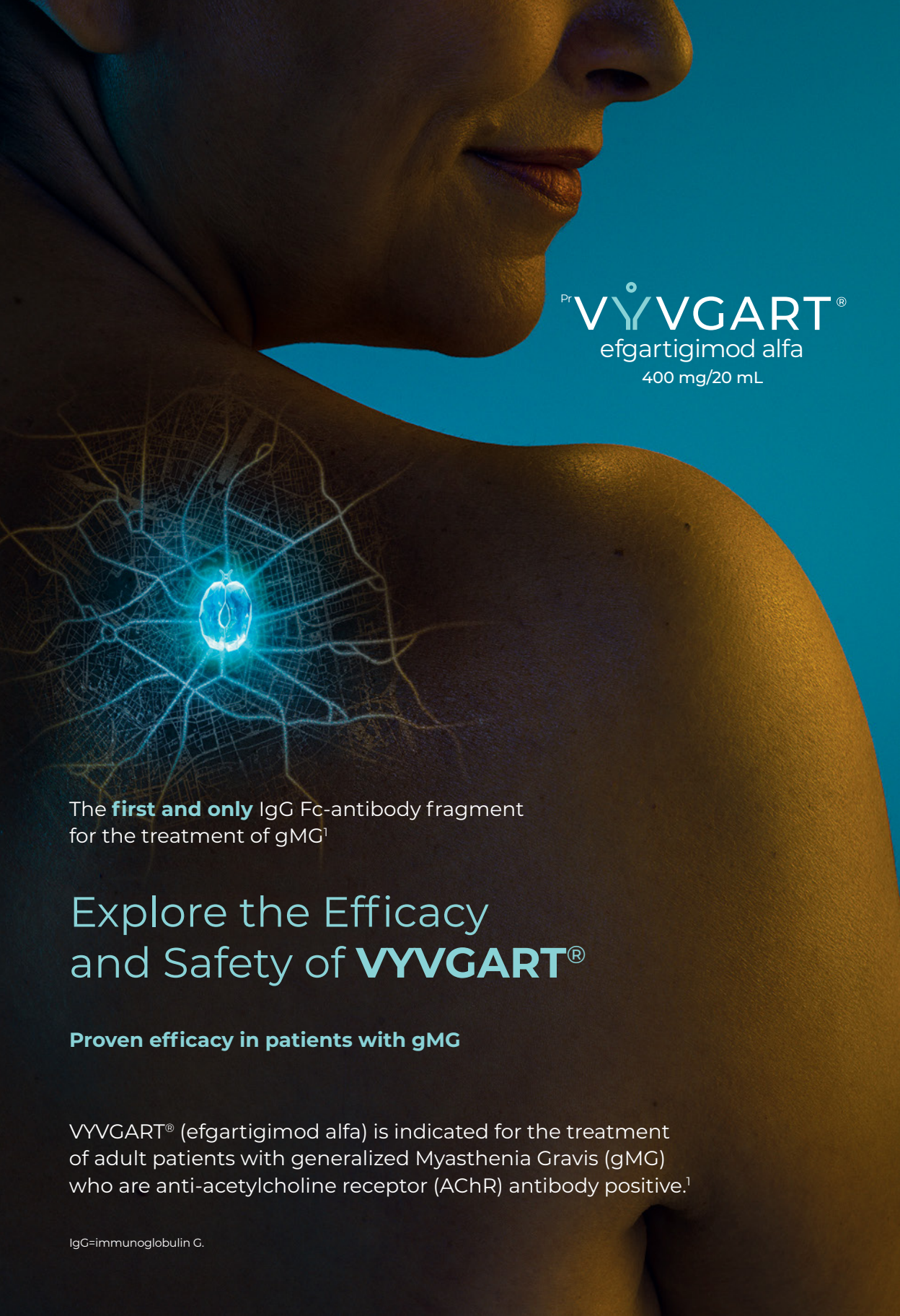


The **first and only** IgG Fc-antibody fragment for the treatment of gMG[1]

Explore the Efficacy and Safety of **VYVGART®**

Proven efficacy in patients with gMG

VYVGART® (efgartigimod alfa) is indicated for the treatment of adult patients with generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.[1]

IgG=immunoglobulin G.

VYVGART® improved daily function in significantly more patients vs. placebo[2†]

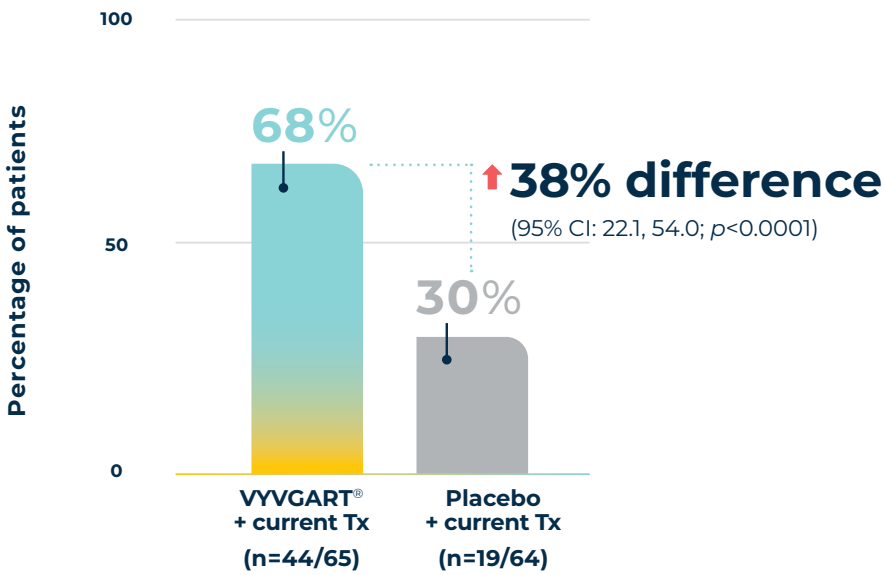
Significantly more patients treated with VYVGART® were MG-ADL responders vs. placebo (AChRAb+ patients; primary endpoint)[2]

MG-ADL responders were defined as:[1]

- ≥2-point reduction in the total MG-ADL score compared to the treatment cycle baseline
- Response sustained for ≥4 weeks
- First reduction occurring no later than 1 week after the last infusion of the cycle

MG-ADL responders

(first treatment cycle)[1,2]



The ADAPT phase 3 clinical trial: A 26-week multicentre, randomized, double-blind, placebo-controlled trial[1†]

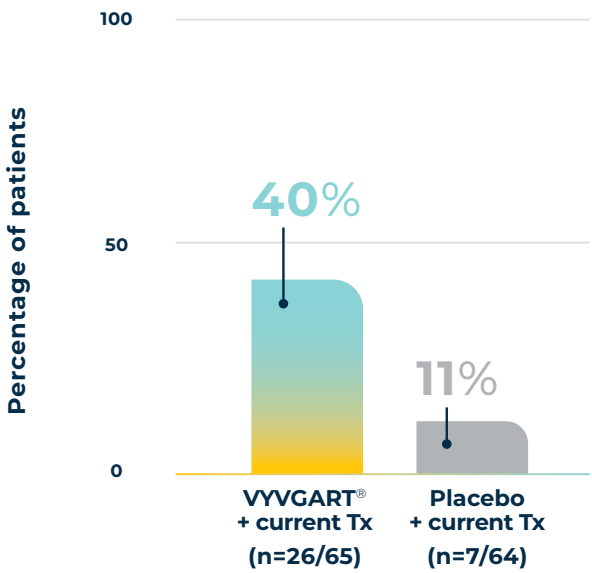
- **167** patients
- **75%** steroid Tx at baseline
- **60%** NSIST Tx at baseline
- **50%** steroid and NSIST Tx at baseline
- **58%** previous thymectomy

Exploratory endpoint: Percentage of AChRAb+ patients that achieved Minimal Symptom Expression (MSE)[2]

The term MSE is used to describe an MG-ADL score of 0 or 1[2]
If a person living with gMG achieves MSE it means they are experiencing little to no gMG symptoms.

MSE data

(first treatment cycle)[2]



Study limitations: Percentage of anti-AChR antibody positive patients with MSE was a prespecified descriptive exploratory analysis not controlled for multiplicity and not powered; therefore, data should be interpreted with caution and conclusions cannot be drawn.[2]

AChR=acetylcholine receptor; MG-ADL=Myasthenia Gravis Activities of Daily Living; MSE=Minimal Symptom Expression; NSIST=nonsteroidal immunosuppressive treatment; Tx=treatment.
† ADAPT was a multicentre, randomized, double-blind, placebo-controlled, phase 3 trial. Patients aged at least 18 years with gMG were eligible to participate in the study, regardless of anti-acetylcholine receptor antibody status, if they had an MG-ADL score of at least 5 (>50% non-ocular), and were on a stable dose of at least one treatment for gMG. Patients were treated with VYVGART® + current treatment, or placebo + current treatment.[2]

VYVGART® reduced muscle weakness in significantly more patients vs. placebo[1,2]

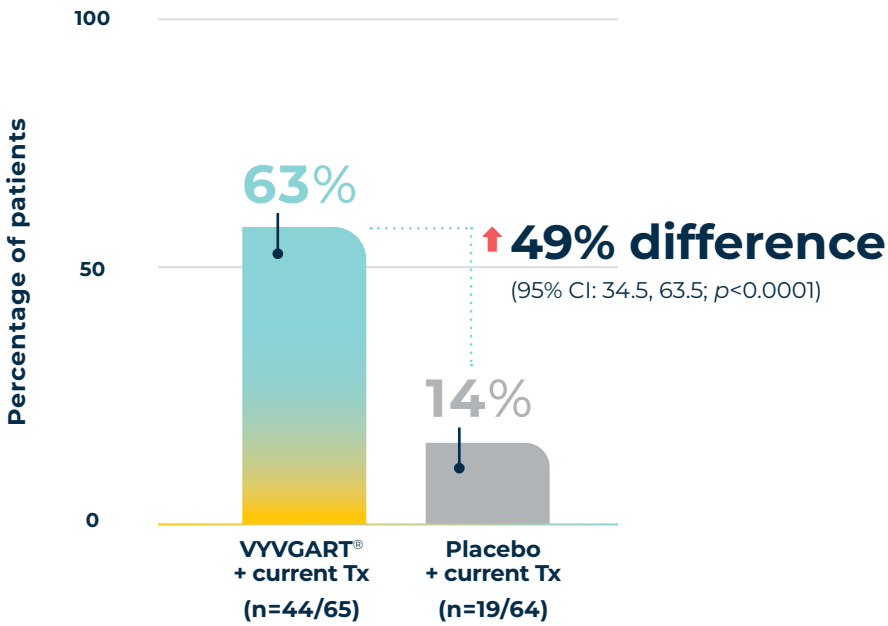
Significantly more patients treated with VYVGART® were QMG responders vs. placebo (AChRAb+ patients; secondary endpoint)[2]

QMG responders were defined as:[1]

- ≥3-point reduction in the total QMG score compared to the treatment cycle baseline
- Response sustained for ≥4 weeks
- First reduction occurring no later than 1 week after the last infusion of the cycle

QMG responders

(first treatment cycle)[1,2]

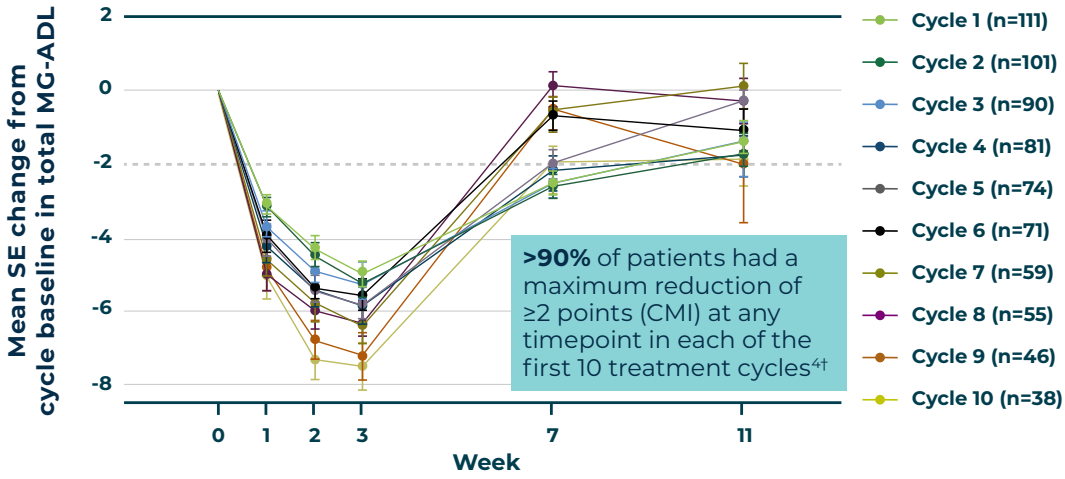


The clinical benefit of VYVGART® was sustained over repeat treatment cycles and maintained over the long term (64 weeks), demonstrating a robust benefit among AChRAb+ patients with gMG.[3]

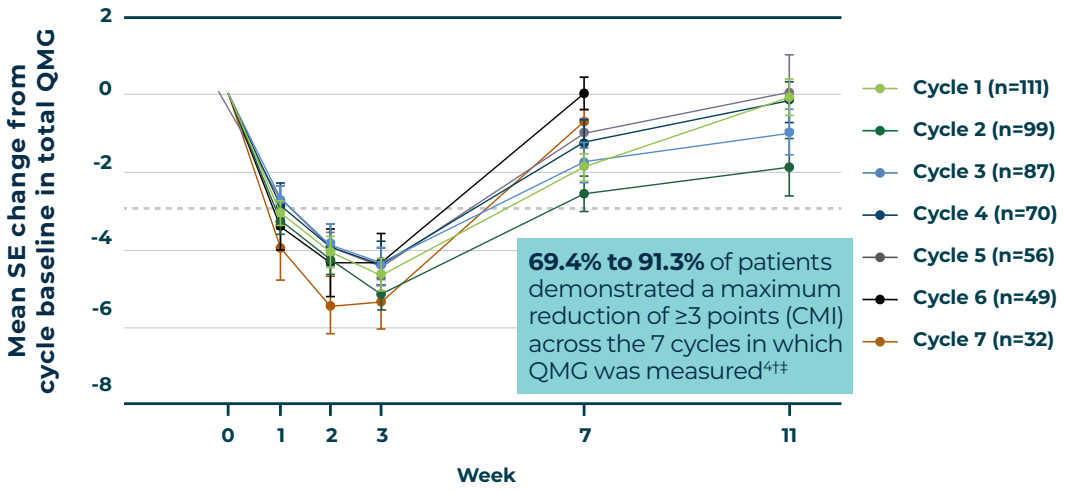
Long-term clinically meaningful improvement in daily function and muscle strength with VYVGART® in ADAPT+[4*†‡]

Long-term clinically meaningful improvement in QMG and MG-ADL scores was consistently observed with VYVGART® in ADAPT+ (AChRAb+ patients)[4†‡]

MG-ADL total score[†‡]



QMG total score[†‡§]



The annualized mean number of cycles was 4.7 cycles per year (median [range] 5.0 [0.5–7.6])[4§]

AChR=acetylcholine receptor; CMI=clinically meaningful improvement; MG-ADL=Myasthenia Gravis Activities of Daily Living; QMG=Quantitative Myasthenia Gravis; SE=standard error; Tx=treatment.

*ADAPT+ was an open-label, single-arm, multicentre, up-to-3-year extension of the pivotal phase 3 ADAPT study. Efgartigimod was administered in treatment cycles of 4 intravenous infusions (one 10 mg/kg infusion per week). Initiation of subsequent treatment cycles was individualized based on clinical evaluation.[4]

†Mean change from cycle baseline in MG-ADL total score, by cycle. Only timepoints with ≥3 participants are included.[4]

‡Data for Week 11 were not graphed for Cycles 6 and 7 because they were unavailable.[4]

§In AChR antibody positive participants (N=95) with ≥1 year of combined follow-up between ADAPT and ADAPT+.[4]

VYVGART®: Demonstrated safety profile[2,4]

	ADAPT[2]						ADAPT+[4]		
	Placebo (n=83) [34.5 PY]			VYVGART® (n=84) [34.9 PY]			VYVGART® (n=145) [217.6 PY]		
	IR[a]	m	n (%)	IR[a]	m	n (%)	IR[a]	m	n (%)
AEs	7.8	270	70 (84)	7.2	252	65 (77)	3.6	783	123 (85)
SAEs[b]	0.3	10	7 (8)	0.1	4	4 (5)[c]	0.2	52	34 (23)[c]
≥1 infusion-related reaction event	0.3	9	8 (10)	0.1	3	3 (4)	0.1	21	15 (10)
Infection AEs	1.2	42	31 (37)	1.6	56	39 (46)	0.8	164	80 (55)
Discontinued due to AEs	0.1	3	3 (4)	0.2	7	3 (4)	0.1	21	12 (8)
Death[c]	-	0	0 (0)	-	0	0 (0)	<0.1	5	5 (3)
Most frequent AEs									
Nasopharyngitis	0.5	17	15 (18)	0.3	12	10 (12)	0.1	24	20 (14)
Upper respiratory tract infection	0.2	5	4 (5)	0.3	11	9 (11)	<0.1	7	6 (4)
Urinary tract infection	0.1	4	4 (5)	0.3	9	8 (10)	0.1	19	13 (9)
Headache	1.1	39	23 (28)	1.2	40	24 (29)	0.4	103	36 (25)
Nausea	0.4	15	9 (11)	0.2	7	7 (8)	0.1	13	9 (6)
Diarrhea	0.4	14	9 (11)	0.2	6	6 (7)	0.1	19	14 (10)
COVID-19[d]	-	0	0 (0)	-	0	0 (0)	0.1	24	22 (15)

a IR was calculated as number of events per total PYs of follow-up.[2,4]
b Serious adverse events in ADAPT+ reported in >1 participant in the total efgartigimod cohort were MG worsening in 7 (4.8%) participants as well as MG crisis, acute respiratory failure, COVID-19, COVID-19 pneumonia, and pneumonia (all in 2 participants [1.4%] each).[2,4]
c None of the deaths in ADAPT+ were related to efgartigimod administration per the principal investigator.[2,4]
d Includes all preferred terms of COVID-19, COVID-19 pneumonia, coronavirus infection, exposure to SARS-COV-2 and SARS-COV-2 test positive.[2,4]

Important safety information[1]

Clinical use:

The safety and efficacy of VYVGART® in children and adolescents below the age of 18 years has not been established. VYVGART® is not indicated for use in pediatric patients.

Contraindications:

- VYVGART® is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.

Other relevant warnings and precautions:

- Increased risk of infections including upper respiratory tract infections and urinary tract infections; monitor patients for signs and symptoms of infections during treatment and delay administration in patients with an active infection until the infection is resolved.
- Vaccination with live or live attenuated vaccines is not recommended in patients taking VYVGART®; for all other vaccines, vaccination should take place at least 2 weeks after the last infusion of a treatment cycle and 4 weeks before initiating the next cycle.
- There is no clinical experience with VYVGART® use and its potential effect on fertility.
- Hypersensitivity and infusion related reactions; monitor patients during administration and for 1 hour thereafter for clinical signs and symptoms of infusion reactions.
- There is no available clinical data on the use of VYVGART® during pregnancy; risk and benefits should be considered prior to administering live or live-attenuated vaccines to infants exposed to VYVGART® *in utero*.
- There is no information regarding the presence of VYVGART® in human milk, the effects on the breastfed infant, or the effects on milk production; a risk to the breastfed newborn/infant cannot be excluded.

For more information:

Please consult the Product Monograph at https://www.argenx.com/product/vyvgart_product_monograph.pdf for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this advertisement. The Product Monograph is also available by calling argenx Medical Information 1-800-731-8917.

AE=adverse event; IR=incidence rate; m=number of events; PY=patient-year; SAE=serious adverse event.

References: 1. VYVGART® Product Monograph. argenx. September 19th, 2023. **2.** Howard JF Jr, *et al.* Safety, efficacy, and tolerability of efgartigimod in patients with generalised myasthenia gravis (ADAPT): a multicentre, randomised, placebo-controlled, phase 3 trial. *Lancet Neurol.* 2021 Jul;20(7):526-536. **3.** Dewilde S, *et al.* Post-hoc analyses from the ADAPT clinical study demonstrate aggregate sustained benefit of Efgartigimod in generalized myasthenia gravis. *Journal of the Neurological Sciences* 2024;466:123264. **4.** Howard JF, *et al.* 2023. Long-Term Safety, Tolerability, and Efficacy of Efgartigimod (ADAPT+): Interim Results From a Phase 3 Open-Label Extension Study in Participants With Generalized Myasthenia Gravis. *Front Neurol*; 14, 1284444.

Pr VYVGART®
efgartigimod alfa
400 mg/20 mL

The **first and only** IgG Fc-antibody fragment for the treatment of anti-AChR antibody positive gMG[1]

IMPROVEMENT IN DAILY FUNCTION[1,2]

68% (n=44/65) of AChRAb+ patients treated with VYVGART® were responders who experienced improvement in daily function vs. 30% (n=19/64) with placebo (p<0.0001)†‡

40% (n=26/65) of AChRAb+ patients treated with VYVGART® achieved MSE (MG-ADL score 0-1) vs. 11% with placebo (p<0.0001)§

REDUCTION IN MUSCLE WEAKNESS[1,2]

63% (n=41/65) of AChRAb+ patients treated with VYVGART® were responders who experienced reduction in muscle weakness vs. 14% (n=9/64) on placebo (p<0.0001)¶

The clinical benefit of VYVGART® was sustained over repeat treatment cycles and maintained over the long term (64 weeks), demonstrating a robust benefit among AChRAb+ patients with gMG[3]

ESTABLISHED SAFETY PROFILE[1]

- The most common adverse reactions (≥10%) seen in patients who received at least one dose of VYVGART® included headache (reported by 29% of VYVGART®-treated patients and 28% of placebo-treated patients), upper respiratory tract infection (reported by 11% of VYVGART®-treated patients and 5% of placebo-treated patients), and urinary tract infection (reported by 10% of VYVGART®-treated patients and 5% of placebo-treated patients)
- Most infections were mild to moderate in severity
- The frequency of reported treatment-emergent AEs did not increase with subsequent treatment cycles

AChR=acetylcholine receptor; AE=adverse event; gMG=generalized Myasthenia Gravis; IgG=immunoglobulin G; MG-ADL=Myasthenia Gravis Activities of Daily Living; MSE=minimal symptom expression; QMG=Quantitative Myasthenia Gravis; Tx=treatment.
† Patients were treated with VYVGART® + current Tx or placebo + current Tx.
‡ MG-ADL response was defined as a ≥2-point reduction in the total MG-ADL score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by Week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.
§ Exploratory endpoint. MSE evaluation occurred at any visit from Week 1 through Week 26.
¶ QMG response was defined as a ≥3-point reduction in the total QMG score compared to the treatment cycle baseline for at least 4 consecutive weeks during the first treatment cycle (by Week 8), with the first reduction occurring no later than 1 week after the last infusion of the cycle.

VYVGART is a registered trademark of argenx.
© 2024 argenx CA-VYV-24-00046E
01/25. All Rights Reserved.

argenx
MyPATH
MEMBER OF INNOVATIVE MEDICINES CANADA

Pr VYVGART®
efgartigimod alfa
400 mg/20 mL