Patient portrayal. Individual results may vary.

VYVGART Hytrulo

ACTIVATE ABILITY IN CIDP[1]

A novel treatment for your adult patients with CIDP. With VYVGART Hytrulo, patients who had improvement in functional ability or strength showed a reduced risk of clinical deterioration vs placebo.[1*†]

*Open-label: Improvement in functional ability was defined as an aINCAT improvement of ≥1 point or an I-RODS improvement of ≥4 points. Improvement in strength was defined as an improvement in mean grip strength of ≥8 kPa. Evidence of improvement occurred at 2 consecutive study visits.[1]

†Clinical deterioration (relapse) was defined as a 1-point increase in aINCAT score at 2 consecutive visits or a >1-point increase in aINCAT score at 1 visit.[1]

aINCAT=adjusted Inflammatory Neuropathy Cause and Treatment; CIDP=chronic inflammatory demyelinating polyneuropathy; I-RODS=Inflammatory Rasch-built Overall Disability Scale; kPa=kilopascals.

INDICATION

VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

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

VYVGART® Hytrulo

(efgartigimod alfa and hyaluronidase-qvfc)

Subcutaneous Injection

180 mg/mL and 2000 U/mL vial

VYVGART Hytrulo: the first novel mechanism for CIDP treatment in 30+ years[1-3]

1958* — Corticosteroids[4]

1979* — PLEX[5]

1985* — IG[3]

2024

Efgartigimod alfa

VYVGART Hytrulo is a coformulation of efgartigimod alfa and hyaluronidase. By depolymerizing hyaluronan, hyaluronidase increases permeability of the subcutaneous tissue.[1]

First and only targeted IgG Fc-antibody fragment for CIDP[1,6†]

- Non–plasma-derived biologic therapy for CIDP[7]
- Targets FcRn, resulting in the reduction of circulating IgG[1]

*Indicates the date of the first published case report of positive clinical efficacy in CIDP.
†Human IgG-derived.[1]
CIDP=chronic inflammatory demyelinating polyneuropathy; Fc=fragment, crystallized; FcRn=neonatal Fc receptor; IG=immunoglobulin; IgG=immunoglobulin G; PLEX=plasma exchange.

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

ADHERE: the largest CIDP trial ever conducted, in 322 adult patients with active disease[1,8,9]

Screening and run-in periods[1,10]

SCREENING: ≤4 WEEKS
Confirmed CIDP diagnosis
Patients:
- Were currently receiving standard-of-care therapy, or
- Were not treated with standard-of-care therapy for ≥6 months before study entry, or
- Had not received prior treatment for CIDP

RUN-IN: ≤12 WEEKS
Confirmed active disease
- Patients discontinued treatment and demonstrated evidence of deterioration
- Patients off treatment with evidence of worsening could skip run-in

Patients with confirmed active disease

≤12 WEEKS

Initial treatment period[1]
Open-label treatment (Stage A)

VYVGART Hytrulo (N=322)
(1,008 mg efgartigimod alfa/ 11,200 units hyaluronidase SC QW)

IDENTIFIED RESPONDERS[1]
Patients who had evidence of improvement at 2 consecutive visits, defined as an aINCAT improvement of ≥1 point, an I-RODS improvement of ≥4 points, or a mean grip strength improvement of ≥8 kPa.

Responders

≤48 WEEKS

Randomized withdrawal period[1,10]
Double blind, placebo controlled (Stage B)

VYVGART Hytrulo (n=111)
(1,008 mg efgartigimod alfa/ 11,200 units hyaluronidase SC QW)

Placebo (n=110)
(2,000 U/mL hyaluronidase SC QW)

PRIMARY ENDPOINT[1]
Time to first clinical deterioration compared to baseline of randomized withdrawal period, defined as a 1-point increase in aINCAT score at 2 consecutive visits or a >1-point increase in aINCAT score at 1 visit.

99% of eligible patients elected to enter the ADHERE+ OLE (n=226/228)[11‡]

‡Participants eligible to roll over to the OLE safety study included those who experienced clinical deterioration in the randomized withdrawal period, completed week 48 of the randomized withdrawal period without deterioration, were in the open-label or randomized withdrawal period and ongoing at the time of the 88th event, and were in the run-in period at the time of the 88th event after performing an early discontinuation visit.[11]

CIDP=chronic inflammatory demyelinating polyneuropathy; OLE=open-label extension; SC=subcutaneous; QW=once weekly.

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ADHERE: the largest CIDP trial ever conducted, in 322 adult patients with active disease[1,8,9]

Screening and run-in periods

The screening period was for a maximum of 4 weeks, and the run-in period was for a maximum of 12 weeks.[10]

At the time of screening, patients had a documented diagnosis of definite or probable CIDP using the 2010 European Federation of Neurological Societies/Peripheral Nerve Society criteria for progressing or relapsing forms.[1]

Patients who were on treatment at screening had been receiving standard-of-care therapy (IVIG, SCIG, or corticosteroids).[1,10]

At the start of the run-in period, patients on treatment needed to discontinue treatment and show evidence of deterioration, which was defined as an aINCAT increase of ≥1 point, an I-RODS decrease of ≥4 points (using the centile metric), or a grip strength decrease of ≥8 kPa.[10]

Patients off treatment who had evidence of worsening were allowed to skip the run-in period.[10]

aINCAT=adjusted Inflammatory Neuropathy Cause and Treatment; CIDP=chronic inflammatory demyelinating polyneuropathy; I-RODS=Inflammatory Rasch-built Overall Disability Scale; IVIG=intravenous immunoglobulin; kPa=kilopascals; SCIG=subcutaneous immunoglobulin.

IMPORTANT SAFETY INFORMATION (cont'd)
Immunization
Immunization with vaccines during VYVGART HYTRULO treatment has not been studied; the safety with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because VYVGART HYTRULO causes a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during VYVGART HYTRULO treatment. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART HYTRULO.

ADHERE: the largest CIDP trial ever conducted, in 322 adult patients with active disease[1,8,9]

Initial treatment period
(Open-label treatment, Stage A)

The initial treatment period was for a maximum of 12 weeks until evidence of improvement occurred at 2 consecutive visits, defined as an aINCAT improvement of ≥1 point, an I-RODS improvement of ≥4 points, or a mean grip strength improvement of ≥8 kPa.[1]

Patients who had evidence of improvement at 2 consecutive visits were eligible to proceed to the randomized withdrawal period.[1]

Randomized withdrawal period
(Double blind, placebo controlled, Stage B)

Responders from the initial treatment period were randomized to evaluate the time to first clinical deterioration (relapse) vs placebo.[1]

The randomized withdrawal period was for a maximum of 48 weeks. If patients had clinical deterioration (relapse), then their participation in the randomized withdrawal period ended. Clinical deterioration (relapse) was defined as a 1-point increase in aINCAT score at 2 consecutive visits or a >1-point increase in aINCAT score at 1 visit from baseline at randomization.[1]

The study stopped when 88 events of relapse occurred in the primary endpoint analysis.[1]

aINCAT=adjusted Inflammatory Neuropathy Cause and Treatment; CIDP=chronic inflammatory demyelinating polyneuropathy; I-RODS=Inflammatory Rasch-built Overall Disability Scale; kPa=kilopascals.

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RANDOMIZED WITHDRAWAL PERIOD (PLACEBO CONTROLLED, STAGE B)

Baseline characteristics of the randomized withdrawal period were similar between treatment groups[1]

Baseline patient characteristics	
Median age	**55 years** (range: 20 to 82 years)
Sex	**64% male**
Race	
• White	**65%**
• Asian	**30%**
• African American	**1%**
Median time since diagnosis	**2.2 years**
Median INCAT score	**3.0**

INCAT=Inflammatory Neuropathy Cause and Treatment.

INITIAL TREATMENT PERIOD (OPEN LABEL, STAGE A)

The majority of patients responded to VYVGART Hytrulo based on an improvement in functional ability or strength[1]

~7 out of 10 patients

69% of patients had improvement in functional ability or strength with VYVGART Hytrulo and entered the randomized withdrawal period (n=221/322).[1]

The initial treatment period (up to 12 weeks) identified VYVGART Hytrulo responders who had improvement in functional ability (defined as an aINCAT improvement of ≥1 point or an I-RODS improvement of ≥4 points) or strength (defined as mean grip strength improvement of ≥8 kPa) at 2 consecutive visits.[1]

aINCAT=adjusted Inflammatory Neuropathy Cause and Treatment; I-RODS=Inflammatory Rasch-built Overall Disability Scale; kPa=kilopascals.

IMPORTANT SAFETY INFORMATION (cont'd)
Hypersensitivity Reactions
In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART HYTRULO or intravenous efgartigimod alfa-fcab. 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 in gMG. 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 for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration. If a hypersensitivity reaction occurs, the healthcare professional should institute appropriate measures if needed or the patient should seek medical attention.

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Significant reduction in the risk of clinical deterioration (relapse) with VYVGART Hytrulo[1]

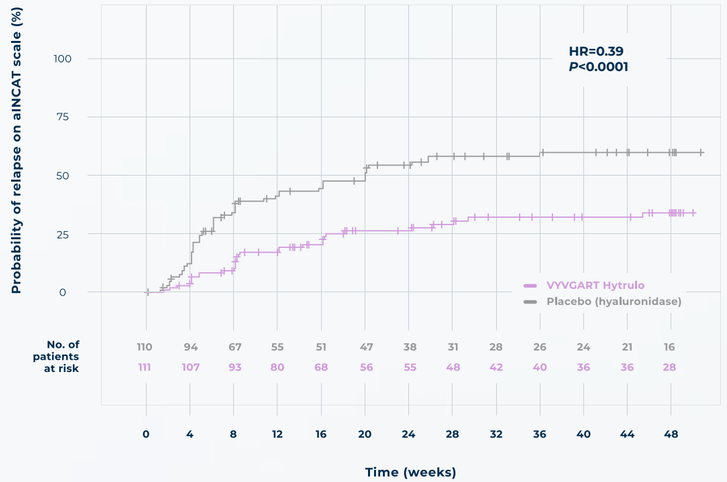
PRIMARY ENDPOINT

61% reduction
in the risk of relapse vs placebo
(HR=0.39 [95% CI: 0.25-0.61; *P*<0.0001])[1]

The primary endpoint for the randomized withdrawal period was the time to first clinical deterioration (relapse), defined as a 1-point increase in aINCAT score at 2 consecutive visits or a >1-point increase in aINCAT score at 1 visit from baseline at randomization.[1]

aINCAT=adjusted Inflammatory Neuropathy Cause and Treatment; CIDP=chronic inflammatory demyelinating polyneuropathy; HR=hazard ratio.

Time to the first aINCAT increase (Kaplan-Meier curve) in patients with CIDP



IMPORTANT SAFETY INFORMATION (cont'd)
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, initiate appropriate therapy. Consider the risks and benefits of readministering 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.

VYVGART Hytrulo has a **demonstrated safety profile**[1]

The overall safety profile observed in patients with CIDP treated with VYVGART Hytrulo was consistent with the known safety profile of VYVGART Hytrulo and of efgartigimod alfa-fcab administered intravenously.[1]

STUDY 1 (ADAPT) FOR gMG[1,12]
Adverse reactions in ≥5% of patients with gMG treated with efgartigimod alfa-fcab IV and more frequently than in placebo-treated patients in Study 1 (Table 1, Prescribing Information)[1]

Study 1	Efgartigimod alfa-fcab (n=84)	Placebo (n=83)
Respiratory tract infection	**33%**	29%
Headache*	**32%**	29%
Urinary tract infection	**10%**	5%
Paraesthesia†	**7%**	5%
Myalgia	**6%**	1%

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea, were observed in patients treated with VYVGART Hytrulo or efgartigimod alfa-fcab IV. Urticaria was also observed in patients treated with VYVGART Hytrulo. Hypersensitivity reactions were mild or moderate and occurred within 1 hour to 3 weeks of administration.[1]

Postmarketing experience with efgartigimod alfa-fcab IV included reports of anaphylaxis and hypotension leading to syncope, as well as infusion-related reactions including hypertension.[1]

*Headache includes migraine and procedural headache.[1]
†Paraesthesia includes oral hypoesthesia, hypoesthesia, and hyperesthesia.[1]
CIDP=chronic inflammatory demyelinating polyneuropathy; gMG=generalized myasthenia gravis; IV=intravenous.

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VYVGART Hytrulo has a **demonstrated safety profile**[1]

The overall safety profile observed in patients with CIDP treated with VYVGART Hytrulo was consistent with the known safety profile of VYVGART Hytrulo and of efgartigimod alfa-fcab administered intravenously.[1]

STUDY 2 (ADAPT-SC) FOR gMG[1,13]

In Study 2, injection site reactions occurred in 38% of patients with gMG receiving VYVGART Hytrulo. These were injection site rash, erythema, pruritus, bruising, pain, and urticaria. In Study 2 and its open-label extension (n=168), 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 first treatment cycle, and the incidence decreased with each subsequent cycle.[1]

STUDY 3 (ADHERE) FOR CIDP[1,8]

In Study 3, injection site reactions occurred in 15% of patients with CIDP treated with VYVGART Hytrulo compared to 6% of patients who received placebo. The most common of these injection site reactions were injection site bruising and injection site erythema. All injection site reactions were mild to moderate in severity. Most injection site reactions occurred during the first 3 months of treatment.[1]

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea, were observed in patients treated with VYVGART Hytrulo or efgartigimod alfa-fcab IV. Urticaria was also observed in patients treated with VYVGART Hytrulo. Hypersensitivity reactions were mild or moderate and occurred within 1 hour to 3 weeks of administration.[1]

Postmarketing experience with efgartigimod alfa-fcab IV included reports of anaphylaxis and hypotension leading to syncope, as well as infusion-related reactions including hypertension.[1]

CIDP=chronic inflammatory demyelinating polyneuropathy; gMG=generalized myasthenia gravis; IV=intravenous.

IMPORTANT SAFETY INFORMATION (cont'd)
ADVERSE REACTIONS
Patients with gMG: In Study 1, the most common (≥10%) adverse reactions in efgartigimod alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. In Study 2, the most common (≥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 in patients with gMG, 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 first treatment cycle, and the incidence decreased with each subsequent cycle.

VYVGART Hytrulo had a **demonstrated safety profile in ADHERE**[1]

The overall safety profile observed in patients with CIDP treated with VYVGART Hytrulo was consistent with the known safety profile of VYVGART Hytrulo and of efgartigimod alfa-fcab administered intravenously.[1]

Adverse reactions in ≥5% of patients with CIDP in the initial treatment period and randomized withdrawal period (adapted from Allen JA et al. Presented at: 76th American Academy of Neurology (AAN) Annual Meeting 2024).[8]

	Initial treatment period (Stage A)	**Randomized withdrawal period** (Stage B)	
Study 3	**VYVGART Hytrulo** (N=322)	**VYVGART Hytrulo** (n=111)	**Placebo** (n=110)
Injection site reactions	**19%**	**15%**	**6%**
Headache	**5%**	**4%**	**2%**
CIDP deterioration	**5%**	**1%**	**1%**
Upper respiratory tract infection	**3%**	**2%**	**10%**
COVID-19	**2%**	**17%**	**13%**

In CIDP, injection site reactions occurred in 15% of patients treated with VYVGART Hytrulo compared to 6% of patients who received placebo.[1]
- All injection site reactions were mild to moderate in severity
- Most injection site reactions occurred during the first 3 months of treatment
- The most common of these injection site reactions were injection site bruising and injection site erythema

CIDP=chronic inflammatory demyelinating polyneuropathy.

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Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

VYVGART Hytrulo offers fast and streamlined treatment administration[1]

Fast ~30-90–second injection

Refers to actual injection time. Patients should be monitored for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration.

Low volume (5.6 mL)

Fixed dose and frequency

The recommended dose of **VYVGART Hytrulo** is 1,008 mg/ 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) administered once weekly as a subcutaneous injection.

VYVGART Hytrulo is administered in an office, infusion center, or at home by a healthcare professional.

IMPORTANT SAFETY INFORMATION (cont'd)
ADVERSE REACTIONS (cont'd)
Patients with CIDP: In Study 3 stage B, the overall safety profile observed in patients with CIDP treated with VYVGART HYTRULO was consistent with the known safety profile of VYVGART HYTRULO and of efgartigimod alfa-fcab administered intravenously. In Study 3, injection site reactions occurred in 15% of patients treated with VYVGART HYTRULO compared to 6% of patients who received placebo. The most common of these injection site reactions were injection site bruising and injection site erythema. All injection site reactions were mild to moderate in severity. Most injection site reactions occurred during the first 3 months of treatment.

Broad access for your patients through My VYVGART® Path

Personalized support for you and your patients on their treatment journey

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

Field Reimbursement Managers are available to directly support your practice and can provide access and reimbursement education, case-specific support, and patient support.*

Access insight

Eligible commercially insured patients may pay as little as **$0 for their co-pay through the VYVGART Co-pay Program.**†

Billing insight

When submitting reimbursement for **VYVGART Hytrulo**, use **HCPCS J-Code J9334** (injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc).

*Case-specific support is limited to patients enrolled in My VYVGART Path.
†Eligible commercially insured patients may pay as little as $0 for VYVGART Hytrulo and may receive a maximum benefit of $25,000 per calendar year for their eligible out-of-pocket costs for the drug and drug administration. Persons residing in MA and RI are not eligible for financial assistance related to administration costs. Please see full Terms and Conditions at VYVGARTCopayTerms.com
CIDP=chronic inflammatory demyelinating polyneuropathy; HCPCS=Healthcare Common Procedure Coding System.

Visit **MyPathEnroll.com** or call **1-833-697-2841** for more information and assistance.

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Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) is indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Infection

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

Immunization

Immunization with vaccines during VYVGART HYTRULO treatment has not been studied; the safety with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because VYVGART HYTRULO causes a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during VYVGART HYTRULO treatment. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART HYTRULO.

Hypersensitivity Reactions

In clinical trials, hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART HYTRULO or intravenous efgartigimod alfa-fcab. 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 in gMG. 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 for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration. If a hypersensitivity reaction occurs, the healthcare professional should institute appropriate measures if needed or the patient should seek medical attention.

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, initiate appropriate therapy. Consider the risks and benefits of readministering 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.

ADVERSE REACTIONS

Patients with gMG: In Study 1, the most common (≥10%) adverse reactions in efgartigimod alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. In Study 2, the most common (≥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 in patients with gMG, 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 first treatment cycle, and the incidence decreased with each subsequent cycle.

Patients with CIDP: In Study 3 stage B, the overall safety profile observed in patients with CIDP treated with VYVGART HYTRULO was consistent with the known safety profile of VYVGART HYTRULO and of efgartigimod alfa-fcab administered intravenously. In Study 3, injection site reactions occurred in 15% of patients treated with VYVGART HYTRULO compared to 6% of patients who received placebo. The most common of these injection site reactions were injection site bruising and injection site erythema. All injection site reactions were mild to moderate in severity. Most injection site reactions occurred during the first 3 months of treatment.

USE IN SPECIFIC POPULATIONS

Pregnancy

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

Lactation

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

Please see the full Prescribing Information.

You may report side effects to the US Food and Drug Administration by visiting http://www.fda.gov/medwatch or calling 1-800-FDA-1088. You may also report side effects to argenx US, Inc, at 1-833-argx411 (1-833-274-9411).

References: 1. VYVGART Hytrulo. Prescribing information. argenx US Inc; 2024. **2.** Brun S et al. *Immuno.* 2022;2:118-131. doi.org/10.3390/immuno2010009 **3.** Vermeulen M et al. *J Neurol Sci.* 1985;70(3):317-326. doi:10.1016/0022-510x(85)90173-x **4.** Hughes RAC et al. *Cochrane Database Syst Rev.* 2017;11(11):CD002062. doi:10.1002/14651858.CD002062.pub4 **5.** Mehndiratta MM et al. *Cochrane Database Syst Rev.* 2015;2015(8):CD003906. doi:10.1002/14651858.CD003906.pub4 **6.** Wolfe GI et al. *J Neurol Sci.* 2021;430:118074. doi:10.1016/j.jns.2021.118074 **7.** Ulrichts P et al. *J Clin Invest.* 2018;128(10):4372-4386. doi:10.1172/JCI97911 **8.** Allen JA et al. Technical release presented at: 76th American Academy of Neurology (AAN) Annual Meeting; April 13-18, 2024; Denver, CO. **9.** Lewis R et al. Poster presented at: American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting; November 1-4, 2023; Phoenix, AZ. **10.** Data on file. REF-02314. argenx US Inc. July 2024. **11.** Data on file. REF-02484. argenx US Inc. July 2024. **12.** ClinicalTrials.gov. NCT03669588. Accessed June 21, 2024. https://www.clinicaltrials.gov/study/NCT03669588 **13.** ClinicalTrials.gov. NCT04735432. Accessed June 21, 2024. https://www.clinicaltrials.gov/study/NCT04735432

VYVGART® Hytrulo
(efgartigimod alfa and hyaluronidase-qvfc)

Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

The first novel mechanism for CIDP treatment in 30+ years[1-3]

First targeted treatment for CIDP[1,6]

VYVGART Hytrulo **targets FcRn**, resulting in the reduction of circulating IgG

Functional ability[1]

With VYVGART Hytrulo, patients who had improvement in functional ability or strength showed a **reduced risk of clinical deterioration** vs placebo*†

Fast injection[1]

~30-90–second injection

Refers to actual injection time. Patients should be monitored for clinical signs and symptoms of hypersensitivity reactions for at least 30 minutes after administration

Scan the QR code or visit VYVGARTHytruloHCP.com/CIDP to learn more.

VYVGART Hytrulo has a demonstrated safety profile[1]

The overall safety profile observed in patients with CIDP treated with VYVGART Hytrulo was consistent with the known safety profile of VYVGART Hytrulo and of efgartigimod alfa-fcab administered intravenously.[1]

In **Study 1 (ADAPT) for gMG**, the most common adverse reactions (reported in at least 10% of patients treated with intravenous efgartigimod alfa-fcab) were respiratory tract infection, headache, and urinary tract infection.[1,12]

In **Study 2 (ADAPT-SC) for gMG**, injection site reactions occurred in 38% of patients receiving VYVGART Hytrulo. These were injection site rash, erythema, pruritus, bruising, pain, and urticaria.[1,13]

In **Study 3 (ADHERE) for CIDP**, injection site reactions occurred in 15% of patients treated with VYVGART Hytrulo compared to 6% of patients who received placebo. These were most commonly injection site bruising and injection site erythema.[1,8]

Hypersensitivity reactions, including rash, angioedema, dyspnea, and urticaria, have occurred with VYVGART Hytrulo or intravenous efgartigimod alfa-fcab. Anaphylaxis, hypotension leading to syncope, and infusion-related reactions have been reported in postmarketing experience with intravenous efgartigimod alfa-fcab. The most frequent symptoms and signs of infusion-related reactions were hypertension, chills, shivering, and thoracic, abdominal, and back pain.[1]

*69% of patients showed evidence of improvement in the initial treatment period (n=221/322). Improvement in functional ability was defined as an aINCAT improvement of ≥1 point or an I-RODS improvement of ≥4 points. Improvement in strength was defined as an improvement in mean grip strength of ≥8 kPa. Evidence of improvement occurred at 2 consecutive study visits.[1]
†61% reduction in risk of relapse vs placebo in the randomized withdrawal period (HR=0.39; $P<0.0001$). Clinical deterioration (relapse) was defined as a 1-point increase in aINCAT score at 2 consecutive visits or a >1-point increase in aINCAT score at 1 visit from baseline at randomization.[1]
aINCAT=adjusted Inflammatory Neuropathy Cause and Treatment; CIDP=chronic inflammatory demyelinating polyneuropathy; FcRn=neonatal Fc receptor; gMG=generalized myasthenia gravis; IgG=immunoglobulin G; I-RODS=Inflammatory Rasch-built Overall Disability Scale; kPa=kilopascals.

Please see Important Safety Information throughout and full Prescribing Information.

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