

Join us for a product theater at **argenx booth 1458**

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

VYVGART[®] Hytrulo
(efgartigimod alfa and
hyaluronidase-qvfc)
Subcutaneous Injection
180 mg/mL and 2000 U/mL vial



Industry Therapeutic Update from argenx: The First and Only IgG Fc-Antibody Fragment for the Treatment of gMG in Adult Patients Who Are Anti-AChR Antibody Positive¹

PRESENTED BY



Perry Shieh, MD, PhD, FAAN

David Geffen School of Medicine
University of California
Los Angeles, CA

**Sunday, April 14
1:00 PM–1:20 PM**



Perry Shieh, MD, PhD, FAAN

David Geffen School of Medicine
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**Monday, April 15
4:00 PM–4:20 PM**



Namita A. Goyal, MD, FAAN

University of California, Irvine
Orange, CA

**Tuesday, April 16
1:00 PM–1:20 PM**

Join us for these presentations at **argenx booth 1458**
during the 2024 AAN Annual Meeting

These sessions do not offer CME credit.

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AAN, American Academy of Neurology; AChR, acetylcholine receptor; CME, continuing medical education; Fc, fragment, crystallized; gMG, generalized myasthenia gravis; IgG, immunoglobulin G.

SELECT IMPORTANT SAFETY INFORMATION AND INDICATION FOR VYVGART AND VYVGART HYTRULO

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.

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-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

Please see Select Important Safety Information throughout and full Prescribing Information for both VYVGART at [VYVGARTHCP.com/PI](https://www.vyvgarthcp.com/PI) and VYVGART HYTRULO at [VYVGARTHCP.com/HYTRULO-PI](https://www.vyvgarthcp.com/HYTRULO-PI).

SELECT IMPORTANT SAFETY INFORMATION (continued)

Infection (continued)

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 appropriate treatment and consider withholding treatment with VYVGART or VYVGART HYTRULO until the infection has resolved.

Immunization

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

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.

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.

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 first treatment cycle, and the incidence decreased with each subsequent cycle.

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. Risks and benefits should be considered prior to administering live or live attenuated 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. 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 the full [Prescribing Information for VYVGART](#) and the full [Prescribing Information for VYVGART HYTRULO](#).

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).

INDICATION

VYVGART® (efgartigimod alfa-fcab) for intravenous infusion and VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection are each indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

References: VYVGART® (efgartigimod alfa-fcab). Package insert. argenx US, Inc.; 2024; VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc). Package insert. argenx US, Inc.; 2024. Wolfe GI, Ward ES, de Haard H, et al. IgG regulation through FcRn blocking: a novel mechanism for the treatment of myasthenia gravis. *J Neurol Sci*. 2021;430:118074. doi:10.1016/j.jns.2021.118074.