



## **argenx Highlights FcRn Leadership with Long-term Data and Transformational Patient Outcomes at the American Academy of Neurology 2025 Annual Meeting**

- *Largest safety data set on FcRn blocking demonstrates consistent, favorable safety profile of VYVGART and VYVGART Hytrulo*
- *gMG patients on VYVGART achieve rapid, substantial, and sustained efficacy across multiple dosing regimens, supporting individualized treatment approach*
- *ADHERE+ oral presentation builds upon evidence of VYVGART Hytrulo driving improved functional ability in CIDP*

**Amsterdam, the Netherlands – March 7, 2025** – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced clinical trial and real-world data for VYVGART® (efgartigimod alfa-fcab) and VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) will be presented at the American Academy of Neurology (AAN) Annual Meeting, taking place in San Diego, CA from April 5-9, 2025.

“Our goal is to help people living with rare autoimmune diseases feel and function the way they did before experiencing life with a debilitating condition. This year at AAN, we are sharing more evidence demonstrating the long-term benefits of VYVGART for patients living with gMG and CIDP,” said Luc Truyen, M.D., Ph.D., Chief Medical Officer at argenx. “Our breadth of data continues to support VYVGART as a leading biologic. It has a proven ability to achieve minimal symptom expression for gMG patients and reduce CIDP symptoms quickly while providing improved functional ability, all with a favorable safety profile. We look forward to engaging in the latest science at AAN to continue pushing the boundaries of helping patients live better.”

Abstracts at AAN will highlight real-world and clinical data demonstrating VYVGART’s sustained clinical improvements, including consistent functional improvement and a favorable safety profile. In addition, presentations support an individualized treatment approach and the ambition for VYVGART to reach patients earlier in the treatment paradigm.

- **Additional dosing approaches achieve clinical improvements in gMG through 126 weeks:** New data from ADAPT-NXT, investigating biweekly or every three-week dosing of VYVGART, demonstrated sustained clinical improvements, including minimal symptom expression (MSE), and consistent long-term safety through 126 weeks.
- **Largest long-term data set of any FcRn blocker in gMG shows sustained safety and efficacy:** ADAPT-SC+ analyses of VYVGART Hytrulo demonstrate consistent safety results and sustained efficacy through nine cycles of treatment.
- **Favorable benefit-risk profile in gMG:** A comparative effectiveness study of emerging immunomodulatory therapies for patients with gMG shows that Fc receptor blockers, particularly VYVGART, show a more favorable benefit-risk profile.
- **Long-term effectiveness in CIDP:** Interim results from the open-label extension ADHERE+ further build upon the largest clinical data set supporting long-term efficacy, including functional improvement and safety of VYVGART Hytrulo in CIDP.
- **Switch from IVIg to efgartigimod in CIDP:** The Phase 4 open-label trial is investigating effective and safe transition from stable IVIg doses to VYVGART Hytrulo within one week after last IVIg dose.

Details for oral and poster presentations at AAN are as follows:

<b>Title</b>	<b>Lead Author</b>	<b>Presentation</b>
<b>Long-term Efficacy of Efgartigimod PH20 SC in Patients with Chronic Inflammatory Demyelinating Polyneuropathy: Interim Results From The ADHERE+ Study</b>	Jeffrey Allen	Oral Presentation #002 S:16 Updates on Nerve and Muscle Disorders Monday, April 7 1:12 PM
<b>Design of a Phase 3 Randomized, Double-Blinded, Placebo-Controlled Study Evaluating the Efficacy and Safety of Subcutaneous Efgartigimod PH20 Administered by Prefilled Syringe in Adults with Ocular Myasthenia Gravis</b>	Carolina Barnett-Tapia	Poster #003 Neighborhood 11 Saturday, April 5 11:45 - 12:45 PM
<b>Long-Term Safety and Efficacy of Subcutaneous Efgartigimod PH20 in Adult Participants with Generalized Myasthenia Gravis: Interim Results of the ADAPT-SC+ Study</b>	Tuan Vu	Poster #005 Neighborhood 11 Saturday, April 5 11:45 - 12:45 PM
<b>Fixed Cycle and Every-Other-Week Dosing of Intravenous Efgartigimod for Generalized Myasthenia Gravis: Part B of ADAPT NXT</b>	Kelly Gwathmey	Poster #004 Neighborhood 11 Saturday, April 5 11:45 - 12:45 PM
<b>Hospitalization Outcomes After Efgartigimod Initiation In Patients with Myasthenia Gravis</b>	A. Gordon Smith	Poster #011 Neighborhood 11 Saturday, April 5 11:45 – 12:45 PM
<b>A Retrospective Claims Study to Investigate Safety Risks Associated with Chronic Inflammatory Demyelinating Polyneuropathy and the Mediating Effects of Immunoglobulin Treatments</b>	Jana Podhorna	Poster #011 Neighborhood 2 Saturday, April 5 11:45 AM – 12:45 PM
<b>Changes In Nonsteroidal Immunosuppressive Treatment Usage Before and After Efgartigimod Initiation in Patients with Myasthenia Gravis</b>	Pushpa Narayanaswami	Poster #015 Neighborhood 11 Saturday, April 5 11:45 – 12:45 PM
<b>Combined Analyses of Participants with Anti-Acetylcholine Receptor Seronegative Generalized Myasthenia Gravis Treated with Efgartigimod Across Clinical Studies</b>	Vera Brill	Poster #029 Neighborhood 11 Saturday, April 5 11:45 - 12:45 PM
<b>Evaluating the Comparative Effectiveness of Emerging Immunomodulatory Therapies for Patients with Generalized Myasthenia Gravis</b>	A. Gordon Smith	Poster #033 Neighborhood 11 Saturday, April 5 11:45 – 12:45 PM

<b>Study Design of Subcutaneous Efgartigimod PH20 in Juvenile Generalized Myasthenia Gravis</b>	Abigail Schwaede	Poster #009 Neighborhood 6 Monday, April 7 5:00 - 6:00 PM
<b>Phase 3 Trial Investigating Impact of Intravenous Efgartigimod in Anti-Acetylcholine Receptor Antibody Negative Generalized Myasthenia Gravis</b>	James F. Howard Jr	Poster #032 Neighborhood 11 Monday, April 7 5:00 - 6:00 PM
<b>First-in-Human Dose Selection and Pharmacokinetics, Safety, Tolerability, and Immunogenicity of ARGX-119, an Agonist Antibody for Human Muscle-Specific Kinase</b>	Tonke van Bragt	Poster #007 Neighborhood 2 Tuesday, April 8 5:00-6:00 PM
<b>Treatment Impact of Efgartigimod PH20 SC in I-RODS Daily Activity Assessment in Patients with Chronic Inflammatory Demyelinating Polyneuropathy: Post hoc Analysis of the Registrational ADHERE Study</b>	Richard Lewis	Poster #025 Neighborhood 11 Tuesday, April 8 5:00 PM – 6:00 PM
<b>Investigating the Pharmacodynamics, Injection Speed, and Usability of Subcutaneous Efgartigimod PH20 Administration Using a Prefilled Syringe</b>	Tiffany Hargraves	Poster #026 Neighborhood 11 Tuesday, April 8 11:45 - 12:45 PM
<b>Transition From Intravenous Immunoglobulin to Efgartigimod PH20 SC in Participants with Chronic Inflammatory Demyelinating Polyneuropathy: A Phase 4 Study in Progress</b>	Yessar Hussain	Poster #026 Neighborhood 11 Tuesday, April 8 5:00 PM – 6:00 PM
<b>COVID-19 Vaccination Response in Participants Across Clinical Trials Investigating Efgartigimod PH20 SC</b>	Ali A. Habib	Poster #029 Neighborhood 11 Tuesday, April 8 11:45 - 12:45 PM

More information on the program is available at [www.aan.com/events/annual-meeting-abstracts#subnav](http://www.aan.com/events/annual-meeting-abstracts#subnav).

See FDA-approved Important Safety Information below, full Prescribing Information for VYVGART, and full Prescribing Information for VYVGART Hytrulo for additional information.

## Important Safety Information

### What is VYVGART® (efgartigimod alfa-fcab)?

VYVGART is a prescription medicine used to treat a condition called generalized myasthenia gravis, which causes muscles to tire and weaken easily throughout the body, in adults who are positive for antibodies directed toward a protein called acetylcholine receptor (anti-AChR antibody positive).

### IMPORTANT SAFETY INFORMATION

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

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

- **Infection.** VYVGART may increase the risk of infection. The most common infections were urinary tract and respiratory tract infections. Signs or symptoms of an infection may include fever, chills, frequent and/or painful urination, cough, pain and blockage of nasal passages/sinus, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain.
- **Allergic Reactions (hypersensitivity reactions).** VYVGART can cause allergic reactions such as rashes, swelling under the skin, and shortness of breath. Serious allergic reactions, such as trouble breathing and decrease in blood pressure leading to fainting have been reported with VYVGART.
- **Infusion-Related Reactions.** VYVGART can cause infusion-related reactions. The most frequent symptoms and signs reported with VYVGART were high blood pressure, chills, shivering, and chest, abdominal, and back pain.

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

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

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

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

The most common side effects of VYVGART are respiratory tract infection, headache, and urinary tract infection. These are not all the possible side effects of VYVGART. Call your doctor for medical advice about side effects. You may report side effects to the US Food and Drug Administration at 1-800-FDA-1088.

Please see the full [Prescribing Information](#) for VYVGART and talk to your doctor.

**What is VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc)?**

VYVGART HYTRULO is a prescription medicine used to treat a condition called generalized myasthenia gravis, which causes muscles to tire and weaken easily throughout the body, in adults who are positive for antibodies directed toward a protein called acetylcholine receptor (anti-AChR antibody positive).

VYVGART HYTRULO is a prescription medicine used for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP)

**IMPORTANT SAFETY INFORMATION**

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

**VYVGART HYTRULO may cause serious side effects, including:**

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

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

**Before taking VYVGART HYTRULO, tell your doctor if you:**

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

**What are the common side effects of VYVGART HYTRULO?**

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

These are not all the possible side effects of VYVGART HYTRULO. Call your doctor for medical advice about side effects. You may report side effects to the US Food and Drug Administration at 1-800-FDA-1088.

Please see the full [Prescribing Information](#) for VYVGART HYTRULO and talk to your doctor.

### **About VYVGART**

VYVGART is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG autoantibodies. It is the first approved FcRn blocker in the United States, EU, China and Canada for the treatment of adults with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive and in Japan for the treatment of adults with gMG who do not have sufficient response to steroids or non-steroidal immunosuppressive therapies (ISTs).

### **About VYVGART Hytrulo**

VYVGART Hytrulo is a subcutaneous combination of efgartigimod alfa, a human IgG1 antibody fragment marketed for intravenous use as VYVGART, and recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology to facilitate subcutaneous injection delivery of biologics. In binding to the neonatal Fc receptor (FcRn), VYVGART Hytrulo results in the reduction of circulating IgG. It is the first-approved FcRn blocker administered by subcutaneous injection. VYVGART Hytrulo is the proprietary name in the U.S. for subcutaneous efgartigimod alfa and recombinant human hyaluronidase PH20. It may be marketed under different proprietary names following approval in other regions.

### **About Generalized Myasthenia Gravis**

Generalized myasthenia gravis (gMG) is a rare and chronic autoimmune disease where IgG autoantibodies disrupt communication between nerves and muscles, causing debilitating and potentially life-threatening muscle weakness. Approximately 85% of people with MG progress to gMG within 24 months<sup>1</sup>, where muscles throughout the body may be affected. Patients with confirmed AChR antibodies account for approximately 85% of the total gMG population<sup>1</sup>.

### **About Chronic Inflammatory Demyelinating Polyneuropathy**

Chronic inflammatory demyelinating polyneuropathy (CIDP) is a rare and serious autoimmune disease of the peripheral nervous system. Although confirmation of disease pathophysiology is still emerging, there is increasing evidence that IgG antibodies play a key role in the damage to the peripheral nerves. People with CIDP experience fatigue, muscle weakness and a loss of feeling in their arms and legs that can get worse over time or may come and go. These symptoms can significantly impair a person's ability to function in their daily lives. Without treatment, one-third of people living with CIDP will need a wheelchair.

### **About ARGX-119**

ARGX-119 is a humanized agonistic monoclonal antibody (mAb) that targets and activates muscle-specific kinase (MuSK) to promote maturation and stabilization of the neuromuscular junction (NMJ). MuSK is a receptor kinase that has a critical role in the structure and function of the NMJ. ARGX-119 is being developed as a potential therapy for patients with neuromuscular disease.

## **About argenx**

argenx is a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases. Partnering with leading academic researchers through its Immunology Innovation Program (IIP), argenx aims to translate immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. argenx developed and is commercializing the first approved neonatal Fc receptor (FcRn) blocker and is evaluating its broad potential in multiple serious autoimmune diseases while advancing several earlier stage experimental medicines within its therapeutic franchises. For more information, visit [www.argenx.com](http://www.argenx.com) and follow us on [LinkedIn](#), [X/Twitter](#), [Instagram](#), [Facebook](#), and [YouTube](#).

## **References**

<sup>1</sup> Behin et al. New Pathways and Therapeutics Targets in Autoimmune Myasthenia Gravis. J Neuromusc Dis 5. 2018. 265-277

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## **Forward-looking Statements**

The contents of this announcement include statements that are, or may be deemed to be, “forward-looking statements.” These forward-looking statements can be identified by the use of forward-looking terminology, including the terms “aim,” “are,” “believe,” “can,” “continue,” “engage,” “may,” and “will” and include statements argenx makes concerning the potential impact of VYVGART and VYVGART Hytrulo for patients; the data for VYVGART and VYVGART Hytrulo that will be presented at the upcoming AAN Annual Meeting; its goal of pushing the boundaries of helping patients live better; the planned agenda for the AAN Annual Meeting; its data showing VYVGART and VYVGART Hytrulo as one of the leading biologics for gMG and CIDP; and its goal of translating immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. argenx’s actual results may differ materially from those predicted by the forward-looking statements as a result of various important factors, including but not limited to, the results of argenx’s clinical trials; expectations regarding the inherent uncertainties associated with the development of novel drug therapies; preclinical and clinical trial and product development activities and regulatory approval requirements; the acceptance of its products and product candidates by its patients as safe, effective and cost-effective; the impact of governmental laws and regulations on its

business; its reliance on third-party suppliers, service providers and manufacturers; inflation and deflation and the corresponding fluctuations in interest rates; and regional instability and conflicts. A further list and description of these risks, uncertainties and other risks can be found in argenx's U.S. Securities and Exchange Commission (SEC) filings and reports, including in argenx's most recent annual report on Form 20-F filed with the SEC as well as subsequent filings and reports filed by argenx with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. argenx undertakes no obligation to publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.