



**argenx Highlights Data Showing Patient Impact Across Multiple Immunology Programs at 2024 American Association of Neuromuscular & Electrodiagnostic Medicine Annual Meeting and Myasthenia Gravis Foundation of America Scientific Sessions**

*Long-term and real-world data of VYVGART® (efgartigimod alfa-fcab) and VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) demonstrate speed of onset, depth of response, and durability of response*

*VYVGART demonstrates consistent, favorable safety profile from follow-up safety data that totals >8,000 patient years; no vaccinations required and no impact on human serum albumin levels*

*Real-world data show more than 50 percent of gMG patients demonstrate substantial and sustained reduction in steroid use following VYVGART initiation*

*argenx continues to expand its reach in neurology through pipeline programs, including empasiprubar advancing in MMN and ARGX-119 in ALS and CMS*

**October 15, 2024 – 7:00am CET**

**Amsterdam, the Netherlands** – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced the presentation of clinical and real-world data across its growing immunology pipeline at the 2024 American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting and Myasthenia Gravis Foundation of America (MGFA) Scientific Sessions in Savannah, GA from October 15-18, 2024.

“VYVGART continues to deliver impactful benefits to patients in terms of safety, speed of onset, depth of response, and durability of response,” said Luc Truyen, M.D., Ph.D., Chief Medical Officer, argenx. “The robust data we are showing at AANEM and MGFA continue to confirm VYVGART as the leading innovative biologic with an established ability to reduce steroid usage, drive minimal symptom expression for gMG patients, and reduce CIDP symptoms quickly. In addition to VYVGART, we are excited to highlight our growing neurology pipeline, including empasiprubar and ARGX-119, through which we can advance our mission of delivering transformative outcomes for even more patients.”

**VYVGART and VYVGART Hytrulo Demonstrate Rapid, Deep and Sustained Responses in gMG and CIDP**

The data presented at AANEM continue to demonstrate the significant impact of VYVGART (including VYVGART Hytrulo), the first-in-class neonatal Fc receptor (FcRn) blocker for people living with generalized myasthenia gravis (gMG) and chronic inflammatory demyelinating polyneuropathy (CIDP). VYVGART is setting a new treatment standard in gMG and has shown rapid, deep and sustained responses, enabling a majority of patients to achieve minimal symptom expression (MSE) with a consistent and favorable safety profile and more than 8,000 patient years of safety data. Based on real-world data, more than half of patients can reduce steroid use by >5mg/day following VYVGART initiation. In CIDP, a majority of patients in the ADHERE trial responded to VYVGART Hytrulo and experienced reduced risk of relapse versus placebo and improvements in motor function and muscle strength, regardless of prior CIDP treatment.

## Highlights from VYVGART data presented at AANEM and MGFA:

- **Early Line Use and Meaningful Steroid Reduction:** VYVGART demonstrates consistent improvement across gMG patient subtypes, including those on mestinon alone, indicating its efficacy in early line use. Real-world gMG data show that at one-year post VYVGART initiation, 55% of patients reduced corticosteroid use by  $\geq 5$  mg/day and 42% of patients had achieved steroid doses of  $\leq 5$  mg/day.
- **Expansion to Seronegative and Ocular MG:** argenx is honoring its long-term commitment to the broader MG community with two Phase 3 studies ongoing in additional MG patient populations, including seronegative (ADAPT-SERON) and ocular MG (ADAPT-OCULUS). Seronegative (AChR-) gMG patients evaluated in VYVGART clinical studies experienced consistent and clinically meaningful MG-ADL improvements, including patients achieving MSE.
- **Sustained Functional Benefit in CIDP:** VYVGART Hytrulo showed sustained functional benefit in motor function and muscle strength, regardless of prior treatment, which was maintained through ADHERE and the open-label extension study (through week 24).
- **Consistent, Favorable Safety Profile:** VYVGART's consistent and favorable safety profile has been established across multiple autoimmune diseases with no increase in the incidence of adverse events with increased exposure. The unique safety profile of VYVGART is further supported by no black box warnings, no labs or immunoglobulin (Ig) monitoring, and no vaccination requirements.

## Advancing Immunology Pipeline Across Two First-in-Class Opportunities to Reach New Patients

argenx will also highlight two additional pipeline candidates, including Phase 2 ARDA data of empasiprubart (anti-C2 inhibitor) for the treatment of multifocal motor neuropathy (MMN), and clinical trial designs of ARGX-119 (muscle-specific kinase (MuSK) agonist) for the treatment of congenital myasthenic syndromes (CMS) and amyotrophic lateral sclerosis (ALS).

Cohort 1 data from the Phase 2 ARDA study will be presented in a poster, showing treatment with empasiprubart for MMN reduced the risk of IVIg retreatment by 91% (HR: 0.09 [95% CI: 0.02–0.44]) and demonstrated significant improvement in grip strength in both hands as compared to placebo. Data from a Patient Global Impression of Change scale show 94.4% of patients said they improved on empasiprubart from the start of the study, compared to 11.1% of placebo patients. As part of its commitment to the MMN community, argenx initiated the iMMersioN longitudinal study of ~150 patients to collect data on the impact of disease and burden of current treatment options on clinical outcomes and quality of life measures. A Phase 3 study of empasiprubart in MMN will start by the end of 2024.

## argenx posters included in MGFA Scientific Sessions

- All MGFA posters to be presented on Tuesday, October 15, 12:00 – 12:45pm ET
- Posters with an asterisk (\*) will also be presented in AANEM scientific program

Full Title	Presentation Details
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Patterns of Efgartigimod Dosing in Clinical Practice in the United States	Poster # MG9
Real-World Reduction in Oral Glucocorticoid Utilization at 1-Year Following Efgartigimod Initiation*	Poster # MG31 / AANEM Poster # 262
Efficacy, Safety, and Pharmacodynamics of Efgartigimod PH20 SC Across Bodyweight Quartiles: A Post hoc Analysis of the ADAPT-SC+ Trial	Poster # MG32
Fixed Cycle and Every-Other-Week Dosing of Intravenous Efgartigimod for Generalized Myasthenia Gravis: Part A of ADAPT NXT*	Poster # MG33 / AANEM Poster # 182
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	Poster # MG38
Phase 3 Trial Investigating Impact of Intravenous Efgartigimod in Anti-Acetylcholine Receptor Antibody Negative Generalized Myasthenia Gravis*	Poster # MG39 / AANEM Poster # 178
Observed Efficacy of Efgartigimod in Generalized Myasthenia Gravis Across Patient Subgroups in the ADAPT-SC+ Study	Poster # MG68
Exploring the Impact of Non-Steroidal Immunosuppressive Drugs and Steroids on the Development of Comorbidities in Patients with Myasthenia Gravis in the National Veterans Affairs Health Network	Poster # MG86
Quality of Life of Patients with Symptomatic Ocular MG: Comparison with the General Population	Poster # MG87
Steroid Use, Toxicity, and Monitoring in Patients With Generalized Myasthenia Gravis: A Survey Of Neurologists In The United States*	Poster # MG89 / AANEM Poster # 235
Comparative Risk-Benefit Profiles of Immunomodulatory Therapies for Patients with Generalized Myasthenia Gravis	Poster # MG98

#### argenx posters included in AANEM Scientific Program

\* Session Times:

- Session I: Wednesday, October 16, 6:15 - 6:45pm ET
- Session II: Thursday, October 17, 9:30 - 10am ET
- Session III: Thursday, October 17, 2:45 - 3:15pm ET

Full Title	Presentation Details*
Long-Term Safety and Efficacy of Efgartigimod PH20 SC in Generalized Myasthenia Gravis: Interim Analysis of Anti-Acetylcholine Receptor Antibody Seronegative Participants in ADAPT-SC+	Poster # 144 Session I & Session II
Combined Analyses of Participants With Anti-Acetylcholine Receptor Seronegative Generalized Myasthenia Gravis Treated With Efgartigimod Across Clinical Studies	Poster # 146 Session I & Session II
Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Efficacy of ARGX-119 in Participants With DOK7 Congenital Myasthenic Syndromes: Phase 1b Study in Progress	Poster # 165 Session I & Session III
Efficacy and Safety of Subcutaneous Efgartigimod PH20SC in Chronic Inflammatory Demyelinating Polyneuropathy: ADHERE Trial Subgroup Analysis	Poster # 176 Session I & Session II
Efficacy and Safety of Subcutaneous Efgartigimod PH20 in Chronic Inflammatory Demyelinating Polyneuropathy: ADHERE/ADHERE+ Trial	Poster # 177 Session I & Session III
Safety Profile of Intravenous Efgartigimod From Clinical Trials in Immunoglobulin G-Mediated Autoimmune Diseases	Poster # 180 Session I & Session II

Safety Profile of Subcutaneous Efgartigimod PH20 From Clinical Trials in Immunoglobulin G–Mediated Autoimmune Diseases	Poster # 181 Session I & Session III
Empasiprubarb (ARGX-117) in Multifocal Motor Neuropathy: Initial Safety and Efficacy Data of the Phase 2 ARDA Study	Poster # 198 Session I & Session II
Long-Term Safety, Tolerability, and Efficacy of Subcutaneous Efgartigimod PH20 in Participants With Generalized Myasthenia Gravis: Interim Results of the ADAPT-SC+ Study	Poster # 212 Session I & Session III
Safety, Tolerability, Efficacy, Pharmacokinetics, and Immunogenicity of ARGX-119 in Patients with Amyotrophic Lateral Sclerosis: A Phase 2a Study in Progress	Poster # 237 Session I & Session II
Risk of Serious Infections and Malignancies in Adult Myasthenia Gravis Patients: A US Claims Database Study	Poster # 251 Session I & Session II
Chronic Steroid Toxicity in Adults With Myasthenia Gravis in the United States Based on Electronic Health Records	Poster # 263 Session I & Session II
Subcutaneous Efgartigimod PH20 in Chronic Inflammatory Demyelinating Polyneuropathy: Key Secondary Outcomes from the ADHERE Trial	Poster # 280 Session I & Session III
Empasiprubarb (ARGX-117) in Multifocal Motor Neuropathy: Baseline Characteristics and MMN Confirmation Committee Outcome of the Phase ARDA Study Cohort 1	Poster # 293 Session I & Session II
COVID-19 Vaccination Response in Participants Receiving Efgartigimod IV or Efgartigimod PH20 SC in ADAPT+ or ADAPT-SC+	Poster # 298 Session I & Session III
Steroid Use, Toxicity, and Monitoring in Patients with Chronic Inflammatory Demyelinating Polyneuropathy: A Survey of Neurologists in The United States	Poster # 306 Session I & Session III
Clinical Outcomes, Disease Course, and Quality of Life in Patients With Multifocal Motor Neuropathy: iMMersioN, Study in Progress	Poster # 307 Session I & Session II

More information on the data presented at the 2024 AANEM Annual Meeting can be found [here](#).

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-and-only 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 (gMG)**

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.

### **About Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)**

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 Empasiprubart**

Empasiprubart (ARGX-117) is a first-in-class humanized monoclonal antibody that binds C2 and blocks activation of both the classical and lectin pathways of the complement cascade, leaving the alternative pathway intact for its antimicrobial properties. By blocking complement activity upstream of C3 and C5, empasiprubart has the potential to reduce tissue inflammation and cellular damage, representing a broad pipeline opportunity across multiple severe autoimmune indications. In addition to multifocal motor neuropathy, argenx is evaluating empasiprubart in delayed graft function following kidney transplant, dermatomyositis and chronic inflammatory demyelinating polyneuropathy.

### **About Multifocal Motor Neuropathy**

Multifocal motor neuropathy (MMN) is a rare, severe, chronic autoimmune disease of the peripheral nervous system. The disease is characterized by slowly progressive, asymmetric muscle weakness mainly of the hands, forearms and lower legs. MMN is often associated with the presence of anti-GM1 IgM autoantibodies, leading to activation of the classical complement pathway, driving subsequent axon damage. High-dose IVIg is the only approved treatment for MMN and patients typically experience disease progression despite therapy, indicating an unmet need for efficacious and better tolerated therapeutic options.

### **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 Congenital Myasthenic Syndromes (CMS)**

Congenital Myasthenic Syndromes (CMS) are a heterogeneous group of rare genetic disorders of the neuromuscular junction (NMJ) that lead to muscle weakness. CMS cases are classified into subtypes depending on the underlying genetic mutation. While clinical features vary widely across and within subtypes, the predominant manifestation of CMS is fatigable weakness. Age of onset varies widely; while many patients are diagnosed in infancy or early childhood, patients with milder phenotypes may not present or be diagnosed until adulthood.

### **About Amyotrophic Lateral Sclerosis (ALS)**

ALS is a neurodegenerative disorder of the brain and spinal cord leading to deteriorating muscle function, weakness and atrophy. The multisystemic nature can have impacts throughout the body with specific signs and symptoms associated with lower motor neuron and upper motor neuron loss. Life expectancy is typically 2.5-5 years from diagnosis.



## **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 in the U.S., Japan, Israel, the EU, the UK, Canada and China. The Company is evaluating efgartigimod in multiple serious autoimmune diseases and 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](#).

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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,” and “will,” and include statements argenx makes regarding the anticipated timing of the initiation of the Phase 3 clinical trial for empasiprubarb in MMN 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 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 in products and product candidates; the acceptance of argenx’s products and product candidates by patients as safe, effective and cost-effective; the impact of governmental laws and regulations on our business; disruptions caused on our reliance of 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.

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