



argenx Presents New Data at AANEM and MGFA Highlighting the Strength and Broad Benefit of VYVGART for Myasthenia Gravis Patients

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- *VYVGART demonstrated clinically meaningful benefit across all AChR-Ab seronegative gMG subtypes in ADAPT SERON, supporting broad role of pathogenic IgGs in disease activity*
- *Final ADAPT SC+ results show ~60% of VYVGART gMG patients achieved minimal symptom expression (MSE), with 88% sustaining MSE for at least 4 weeks*
 - *Real world data show >70% of patients treated with VYVGART meaningfully reduced glucocorticoid use while maintaining clinical benefit*

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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 new data further highlighting the efficacy and safety of VYVGART® (IV: efgartigimod alfa-fcab and SC or Hytrulo: efgartigimod alfa and hyaluronidase-qvfc) across generalized myasthenia gravis (gMG) patient populations at the 2025 American Association of Neuromuscular & Electrodagnostic Medicine Annual Meeting (AANEM) and Myasthenia Gravis Foundation of America (MGFA) Scientific Session in San Francisco from October 29 – November 1, 2025.

The data presented feature pivotal Phase 3 results from the ADAPT SERON trial in acetylcholine receptor antibody (AChR-Ab) seronegative patients, interim findings from the ADAPT Jr study in adolescents, a real-world claims analysis showing significantly reduced steroid use among patients treated with VYVGART, long-term outcomes from VYVGART SC treatment with the majority of patients achieving minimal symptom expression (MSE), and a range of other important results. Collectively, these data provide strong evidence of VYVGART's potential to improve outcomes across the full spectrum of gMG patient populations.

"Our latest data reflect argenx' ambition to deliver transformational impact for all people living with MG globally with rapid and significant functional improvements sustained over time, regardless of MG disease subtype," said Luc Truyen, M.D., Ph.D., Chief Medical Officer, argenx. "Each new VYVGART study in MG is contributing to redefining treatment standards for patients seeking to regain quality of life and return to normal daily activities – a significant proportion of whom achieve this standard. And we're not done yet."

First dedicated study to date of AChR-Ab seronegative gMG confirms VYVGART's potential to be a targeted, effective, and safe treatment for patients living with gMG, regardless of autoantibody status (MGFA Oral Presentation #101)

- The Phase 3 ADAPT SERON study met its primary endpoint (p-value=0.0068), demonstrating that AChR-Ab seronegative gMG patients treated with VYVGART achieved a statistically significant improvement in MG-ADL (Myasthenia Gravis Activities of Daily Living) total score compared to placebo after four weeks.
- In the overall population, mean change from baseline in patients treated with VYVGART was a clinically meaningful 3.35 point improvement in MG-ADL total score at week 4. These positive results in MG-ADL score mean patients experienced significant improvements in one or a combination of their abilities in breathing, eating, eyesight and motor functions.
- Improvements in MG-ADL and QMG (Quantitative Myasthenia Gravis score) among patients treated with VYVGART were increasingly pronounced across subsequent treatment cycles in the overall population and in all patient subgroups – MuSK+, LRP4+, triple seronegative gMG.
- VYVGART was well tolerated across AChR-Ab seronegative subtypes and consistent with the established safety profile in patients with AChR-Ab seropositive gMG and other indications. No new safety concerns were identified.
- Results from the ongoing ADAPT SERON study indicate that pathogenic IgGs are an underlying driver of gMG across patient subtypes, regardless of autoantibody status.
- argenx plans to share these results with the U.S. FDA and seek expansion of the VYVGART label to include adult AChR-Ab seronegative gMG patients across all three subtypes.

"The ADAPT SERON trial showed that efgartigimod generated tangible improvements in daily functioning, marking an important advancement for the field and for seronegative patients seeking better disease control. Patients with seronegative gMG,

in particular, have historically lacked effective treatment options. Collectively, these findings highlight that efgartigimod has the potential to deliver meaningful and progressive benefits for patients regardless of antibody status, with its therapeutic impact strengthening through continued treatment,” said James F. Howard Jr., M.D., Professor of Neurology (Neuromuscular Disease), Medicine and Allied Health, Department of Neurology, The University of North Carolina at Chapel Hill School of Medicine and Principal Investigator for the ADAPT SERON trial.

Addressing Unmet Need in Adolescent gMG Patients (MGFA Oral Presentation #113)

- Interim results from the Phase 2/3 ADAPT Jr study showed that VYVGART improved outcomes in adolescents (ages 12–17) with gMG, offering the potential to address a patient population with high unmet needs. Reduction in total IgG and AChR-Ab levels were similar to outcomes in adult gMG patients. VYVGART was well-tolerated and had a favorable safety profile.

Reducing Steroid Use in Real-World Practice (MGFA Oral Presentation #100)

- A retrospective cohort study using real-world evidence showed that long-term VYVGART treatment was associated with substantial and progressive reductions in oral glucocorticoid (GC) use among adults with gMG. A majority of patients (72.5%) achieved meaningful steroid tapering – defined as at least a 1 mg per day reduction from baseline.
- At 18 months, the average daily GC dose for patients receiving VYVGART decreased by more than 50% (from 16.6 to 7.5 mg/day), with most patients (55%) receiving an average daily GC dose of 5 mg/day or less, and 30% of patients receiving no GC. Improvements in MG-ADL scores of ~5 points were observed among patients with available data, supporting the clinical benefit of steroid tapering alongside maintained disease control.

Demonstrating Sustained MSE and Favorable Safety Profile in Long-Term Treatment (AANEM Poster Presentation #12)

- Final results from the ADAPT-SC+ open-label extension study demonstrated that VYVGART SC was well-tolerated during 459.4 participant-years of follow-up and up to 33 treatment cycles.
- Clinically meaningful improvements in mean MG-ADL total scores were observed in AChR-Ab+ participants as early as Week 1 and were sustained through Week 163. 59.2% of AChR-Ab+ participants achieved MSE (MG-ADL score of 0 or 1) at least once, while 88.1% of those sustained minimal symptom expression for at least 4 weeks. No new safety signals were identified with long-term use.

More information on the data presented at the 2025 AANEM Annual Meeting can be found [here](#).

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.

About VYVGART and VYVGART Hytrulo

VYVGART® (efgartigimod alfa fcab) is a first-in-class human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG autoantibodies. VYVGART® Hytrulo is a subcutaneous combination of efgartigimod alfa (VYVGART) and recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology to facilitate subcutaneous injection delivery of biologics. VYVGART is approved for generalized myasthenia gravis (gMG) and immune thrombocytopenia (Japan only). VYVGART Hytrulo is approved for gMG and chronic inflammatory demyelinating polyneuropathy (CIDP). VYVGART Hytrulo may be marketed under different proprietary names in other regions.

ADAPT SERON Study Design

The Phase 3 ADAPT SERON study is a randomized, double-blind, placebo-controlled, multi-center study evaluating the safety and efficacy of efgartigimod in adults with AChR-Ab seronegative gMG (n=119) across North America, Europe, China, and the Middle East. Part A randomized participants (1:1) received 4 once-weekly infusions of efgartigimod IV or placebo, followed by a 5-week follow-up and primary analysis. Part B is an open-label extension: participants receive 2 fixed cycles of 4 once-weekly efgartigimod infusions (4-week interval between cycles); from cycle 3 onward, additional cycles could be started ≥ 1 week after the last administration of the previous cycle, based on clinical status. The primary endpoint is the MG-ADL total score change from baseline to day 29 in part A. Other scales of evaluation include QMG, MG-QoL 15r, MGC, and EQ-5D-5L VAS. Enrolled participants had a confirmed MG diagnosis by an independent panel of experts, and an MG-ADL total score of 5 or greater. Participants were on a stable dose of at least one gMG treatment prior to randomization, including acetylcholinesterase inhibitors, corticosteroids or nonsteroidal immunosuppressive drugs. Participants were eligible to enroll in ADAPT SERON if they were AChR-Ab seronegative, which included participants who are MuSK-Ab seropositive, LRP4-Ab seropositive, or triple seronegative.

MG-ADL is a validated measure of disease activity in patients living with myasthenia gravis, which evaluates the functional impact of symptoms on daily activities such as speaking, chewing, swallowing, breathing, and limb strength.

ADAPT Jr Study Design

ADAPT Jr is an ongoing, open-label, multi-center clinical trial evaluating VYVGART in juvenile patients (ages 2 to <18 years) with anti-acetylcholine receptor (AChR) antibody positive generalized myasthenia gravis (gMG). The trial includes sites across the United States, Canada, and Europe. Key assessments include pharmacokinetics, immunogenicity, safety, tolerability, and clinical effect measured by MG-ADL, QMG, EQ-5D-Y, and pediatric fatigue scores. The primary objective is to confirm age-appropriate dosing; secondary endpoints include evaluating efgartigimod's safety and activity in children and adolescents living with gMG.

IQVIA Real-World Steroid Tapering Study Design

The IQVIA steroid tapering study is a retrospective, real-world analysis evaluating changes in oral glucocorticoid (GC) use among adults with generalized myasthenia gravis (gMG) who initiated and continued VYVGART for at least 18 months. Patients were identified using the U.S. IQVIA Longitudinal Access and Adjudication Data (LAAD) medical and pharmacy claims database between April 2016 and January 2025. MG-ADL (Myasthenia Gravis Activities of Daily Living) data were integrated from the My VYVGART Path patient support program to provide additional clinical context. Glucocorticoid average daily dose (ADD) was evaluated at multiple time points, including baseline (90 days prior to therapy) and 18 months after starting VYVGART. The study included 168 adults (mean age: 59.7 years; 44% female) with chronic GC use prior to VYVGART initiation. Glucocorticoid average daily dose (ADD) was assessed at baseline (90 days pre-VYVGART) and at 18 months (days 515–545 post-initiation). This study provides real-world insights into steroid tapering practices and treatment outcomes among VYVGART-treated gMG patients in the United States.

ADAPT-SC+ Study Design

ADAPT-SC+ is a Phase 3, multicenter, open-label extension study evaluating the long-term safety, tolerability, and efficacy of VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) in adult patients with generalized myasthenia gravis (gMG) who previously completed the ADAPT-SC or ADAPT+ studies. Participants received individualized treatment cycles of subcutaneous efgartigimod PH20, with flexible intervals based on clinical need, for up to 33 cycles and over 459.4 participant-years of follow-up. The study's primary objectives were to assess the long-term safety and sustained clinical effectiveness of VYVGART Hytrulo in a real-world, antibody-positive gMG population. Efficacy was primarily evaluated using the Myasthenia Gravis Activities of Daily Living (MG-ADL) score, a validated measure of disease impact on everyday function.

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 months¹, where muscles throughout the body may be affected. Patients with confirmed AChR antibodies account for approximately 85% of the total gMG population.

About AChR-Ab seronegative gMG

gMG is a rare, chronic, neuromuscular autoimmune disease caused by pathogenic IgGs targeting the neuromuscular junction (NMJ), resulting in impaired neuromuscular transmission and debilitating and potentially life-threatening muscle weakness and chronic fatigue. Approximately 80% of patients with gMG have detectable antibodies against the AChR in sera, and these patients are diagnosed as AChR-Ab seropositive gMG. Approximately 20% of patients with gMG do not have detectable serum antibodies directed against AChR and are referred to as AChR-Ab seronegative gMG. These patients may have detectable autoantibodies targeting other NMJ proteins, such as muscle-specific tyrosine kinase (MuSK) and low-density lipoprotein receptor-

related protein 4 (LRP4), or others. Anti-MuSK antibodies are detected in approximately 1-10% of patients with gMG, while anti-LRP4 antibodies are detected in approximately 1-5% of patients with gMG. About 10% of patients do not have any detectable autoantibodies against AChR, MuSK or LRP4. These triple seronegative patients have historically been excluded from studies and have a higher disease burden and unmet medical need compared to patients with detectable autoantibodies. Currently, there are no approved treatments available for patients with anti-LRP4 antibodies or for triple seronegative patients.

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 and follow us on [LinkedIn](#), [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 “advance,” “aim,” “ambition,” “can,” “committed,” “continue,” “deliver,” “goal,” “improve,” “may,” “potential,” and “will” and include statements argenx makes concerning VYVGART’s potential to improve outcomes across the full spectrum of gMG patient populations; its ambition to deliver transformational impact for all people living with MG globally with rapid and significant functional improvements sustained over time, regardless of specific MG disease subtype; VYVGART’s potential to be a targeted, effective, and safe treatment for patients living with gMG; efgartigimod’s potential to deliver meaningful and progressive benefits for patients regardless of antibody status, with its therapeutic impact strengthening through continued treatment; its plans to share its Phase 3 results from the ADAPT SERON trial results with the U.S. FDA and seek expansion of the VYVGART label to include adult AChR-Ab seronegative gMG patients across all three subtypes; its commitment to improve the lives of people suffering from severe autoimmune diseases; its aim to target unmet need in adolescent gMG patients; its goal of translating immunology breakthroughs into a world-class portfolio of novel antibody-based medicines; its commercialization of the first approved neonatal Fc

receptor (FcRn) blocker and evaluation of its broad potential in multiple serious autoimmune diseases; and its advancement of several earlier stage experimental medicines within its therapeutic franchises. 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, including tariffs, export controls, sanctions and other 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.