



## **argenx Highlights VYVGART Data at AAN 2025 Setting New Standard in Sustained Efficacy and Improved Quality of Life Measures for Patients Living with gMG and CIDP**

- *ADAPT-NXT data demonstrate consistent, sustained disease control across dosing schedules, further supporting individualized VYVGART dosing for gMG patients*
- *ADHERE+ oral presentation features long-term CIDP data demonstrating VYVGART Hytrulo's durable efficacy, sustained functional improvements and favorable safety profile*
- *argenx continues to advance a robust neuromuscular pipeline of clinical candidates; first-in-human data of ARGX-119 (MuSK agonist) support pipeline-in-a-product development plan*

**April 8, 2025, 7:00 AM 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 15 abstracts, including an oral presentation, at the 2025 American Academy of Neurology (AAN) Annual Meeting from April 5 – 9, 2025 in San Diego, CA. The presentations showcase long-term data of VYVGART® (IV: efgartigimod alfa-fcab and SC or Hytrulo: efgartigimod alfa and hyaluronidase-qvfc) demonstrating sustained disease control of generalized myasthenia gravis (gMG) and chronic inflammatory demyelinating polyneuropathy (CIDP) with a favorable safety profile.

argenx also highlighted its commitment to reach the broader MG patient community with two ongoing label expansion studies in ocular myasthenia gravis (oMG) and seronegative MG (snMG). In addition, first-in-human data were presented for the company's third clinical candidate, ARGX-119 (MuSK agonist), which is being evaluated in disorders of the neuromuscular junction (NMJ), including congenital myasthenic syndromes (CMS).

"The data presented at AAN underscore VYVGART and VYVGART Hytrulo's differentiated efficacy and safety profile, connecting data from our long-term studies to what matters most to gMG and CIDP patients, which is durable, significant quality of life improvements," said Luc Truyen, M.D., Ph.D., Chief Medical Officer, argenx. "The extensive data from ADAPT-NXT reinforce the sustained efficacy in patients living with gMG and showcase the opportunity of individualized VYVGART treatment across fixed cycles or every two- or three-week dosing. Also, our long term ADHERE+ data highlight the strength of VYVGART Hytrulo to meaningfully impact motor function and muscle strength for patients with CIDP. Overall, the data we are sharing at AAN reinforce our commitment to the neuromuscular community and further solidify VYVGART as a leading biologic to redefine patient outcomes."

### **VYVGART Sets New Benchmark of Sustained Efficacy and Safety for Patients with gMG**

- **Sustained disease control achieved across multiple dosing approaches:** ADAPT-NXT Part B data demonstrate clinically meaningful improvements as early as Week 1 with both bi-weekly and every three-week dosing schedules of VYVGART. Over the course of the study (126 weeks), 75% of patients showed sustained efficacy, achieving 2-points or more of improvement in MG

activities of daily living (MG-ADL score) during more than 75% of study visits. In addition, more than half (56.5%) of participants achieved minimal symptom expression (MSE) during the study. ADAPT NXT data support multiple options to individualize treatment for patients living with gMG. (Poster P1.004)

- **Consistent efficacy and safety results over nine treatment cycles:** Interim results of ADAPT-SC+ demonstrate consistent and repeatable improvements in MG-ADL and MG Quality of Life (MG-QoL) scores in gMG patients treated with VYVGART Hytrulo. There was no observed increase in infections or injection-site reactions over nine cycles of treatment. Also, the proportion of patients able to achieve MSE was consistent across multiple cycles. (Poster P1.005)

### **VYVGART Hytrulo Delivers Long-term Functional Improvements and Favorable Safety Profile for Patients with CIDP**

- **Significant functional improvements and rapid stabilization:** ADHERE+ data demonstrate VYVGART Hytrulo delivers long-term clinical efficacy. Study results report functional improvements across aINCAT disability scores (>1-point), grip strength (>17 kPa) and I-RODS scale (>8 points) at week 36 compared to baseline at entry to standard of care withdrawal phase. In addition, the majority of ADHERE patients who relapsed during randomized treatment withdrawal stage, restabilized on VYVGART – 50% as early as week 4. Treatment-emergent adverse events (TEAEs) were consistent with label and no new events, nor increased rate or severity of TEAEs were reported with longer treatment with VYVGART Hytrulo. (Oral Presentation S16.002)
- **Real-world insights on transitioning from IVIg to VYVGART Hytrulo:** The ADHERE Phase 4 switch open-label study will build upon the ADHERE registrational trial with new data evaluating the transition of patients from a stable dose of IVIg to VYVGART Hytrulo in a one-week transition period (Poster P10.026). Currently, real-world data of 1,316 CIDP patients (as of Jan. 31, 2025) treated with VYVGART Hytrulo show that 3.3% of patients reported any general CIDP worsening. (Symposium: ITU From Discovery to Practice: FcRn Blockade and its Role in CIDP and gMG)

### **Pipeline Targets Unmet Needs in Underserved Patient Communities**

- **First-in-human Phase 1 study supports continued investigation of ARGX-119:** Across multiple and single dosing regimens, data from ARGX-119 show a favorable safety profile with no new safety signals observed, supporting further development as a treatment for patients with disorders of the NMJ. (Poster P10.007)
- **Expansion to Seronegative and Ocular MG:** argenx is pursuing label extension for VYVGART to broaden its impact with the MG community, including through two Phase 3 studies for seronegative gMG (ADAPT-SERON) and ocular MG (ADAPT-OCULUS). The ADAPT-SERON study is supported by data from seronegative patients in prior VYVGART studies showing consistent and clinically meaningful MG-ADL improvements, including patients achieving MSE. (Poster P1.029)

Full study details can be found at [2025 American Academy of Neurology Abstract Website](#)

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 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, which facilitates 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.

### **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 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 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,” “expect,” “may,” and “will” and include statements argenx makes concerning the potential impact of VYVGART, VYVGART Hytrulo and ARGX-119 for patients; the data for VYVGART, VYVGART Hytrulo and ARGX-119 as well as clinical studies, including ADAPT-NXT and ADHERE+; its commitment to reach the broader MG patient community with two ongoing label-expansion in oMG and snMG; its commitment to improve the lives of people suffering from severe autoimmune diseases; its goal to continue to advance a robust neuromuscular pipeline of clinical candidates; its view that first-in-human data of ARGX-119 support pipeline-in a-product development plan; the ability for ADAPT-NEXT to reinforce the sustained efficacy

in patients living with gMG and showcase the opportunity of individualized VYVGART treatment; the ability of VYVGART Hytrulo to meaningfully impact motor function and muscle strength for patients with CIDP; its commitment to the neuromuscular community; its commitment to further solidify VYVGART as a leading biologic to redefine patient outcomes; its expectations regarding the ADHERE Phase 4 switch open-label study; its aim to target unmet needs in underserved patient communities; 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, 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.