



argenx Delivers on Promise to Transform Patient Expectations in Autoimmunity at American Academy of Neurology 2024 Annual Meeting

ADHERE data presentation will highlight first potential innovation for CIDP patients in 30 years

Abstracts reflect real-world value and consistent efficacy and safety profile associated with long-term use of VYVGART® and VYVGART® Hytrulo in gMG patients

March 7, 2024, 10:01 pm 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 that eight abstracts, including two oral presentations, featuring clinical trial and real-world data for VYVGART (efgartigimod alfa-fcab) and VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) in rare autoimmune diseases will be presented at the American Academy of Neurology (AAN) Annual Meeting, taking place in Denver, CO from April 13-18, 2024.

“We are opening a new chapter for the VYVGART portfolio,” said Luc Truyen, M.D., Ph.D., Chief Medical Officer at argenx. “While VYVGART continues to reach more gMG patients globally, we are also striving to bring meaningful benefits to people living with CIDP – a community which has been awaiting innovation for 30 years. We are excited to present a broad set of data at AAN this year that collectively demonstrate how we are delivering on our promise to transform patients’ lives with innovative treatments.”

Transforming Autoimmunity by Targeting FcRn

Findings from the ADHERE study of VYVGART Hytrulo in chronic inflammatory demyelinating polyneuropathy (CIDP) will be presented for the first time in an oral presentation during the Clinical Trials Plenary Session, taking place on Tuesday, April 16, 2024. These positive data from the ADHERE study have been submitted to the FDA for potential approval of VYVGART Hytrulo in CIDP with a PDUFA target action date of June 21, 2024.

In addition to the full ADHERE data, the AAN presentations will highlight clinical trial and real-world data showcasing the broad opportunity with VYVGART, a first-in-class neonatal FC receptor (FcRn) inhibitor, and VYVGART Hytrulo, to deliver significant value to the generalized myasthenia gravis (gMG) patient community by driving consistent and repeatable improvements across patient subtypes, a favorable and predictable safety profile, and the ability to individualize treatment across both intravenous and subcutaneous administration and dosing schedules.

- **Achievement of MSE enables significant quality of life improvements:** ADAPT/ADAPT+ demonstrate that >40% of patients achieve minimal symptom expression (MSE) across both studies. Patients achieving MSE experience quality of life outcomes comparable to healthy populations, suggesting MSE could be a primary goal of gMG treatment.

- **Favorable safety profile across IgG-mediated autoimmune diseases:** A review of safety findings across multiple studies of VYVGART in IgG-mediated autoimmune diseases showed VYVGART was consistently well tolerated across all indications and doses studied.
- **ADAPT NXT evaluated additional individualized dosing regimens for initiating long-term treatment:** Data from the Phase 3b ADAPT NXT study will provide important guidance on different treatment regimens, which will allow for additional individualization of VYVGART treatment.
- **Potential for tapering of oral corticosteroids (OCS) post-VYVGART initiation:** Long-term OCS use continues to be a significant burden on people living with autoimmune disease and reducing or tapering OCS may alleviate the risk of many adverse events related to long-term usage. Early insights into OCS utilization post-efgartigimod initiation in gMG patients indicate that a substantial proportion reduced OCS usage over the first 6 months of treatment.
- **Cost-effectiveness of VYVGART compared to chronic intravenous immunoglobulin (IVIg):** Findings from a cost-effectiveness analysis of VYVGART versus chronic IVIg for the treatment of gMG showed that, over a lifetime, VYVGART provided greater benefit at lower costs.

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

Title	Lead Author	Presentation
Efficacy, Safety, and Tolerability of Efgartigimod in Patients With Chronic Inflammatory Demyelinating Polyneuropathy: Results From the ADHERE Trial	Jeffrey Allen	Oral Presentation during Clinical Trial Plenary Session Tuesday, April 16, 9:15-11:30 a.m. MT
Real-world Reduction in Oral Corticosteroid Utilization following Efgartigimod Initiation in Patients Living with Generalized Myasthenia Gravis	Neelam Goyal	Oral Presentation Wednesday, April 17 3:42 p.m. MT
Cost-effectiveness Analysis of Efgartigimod versus Chronic Intravenous Immunoglobulin (IVIg) for Treatment of Acetylcholine Receptor Antibody Positive (AChR-Ab+) Generalized Myasthenia Gravis (gMG) in Canada	Zaeem Siddiqi	Poster Presentation Monday, April 15 11:45 a.m.-12:45 p.m. MT
Overview of the Safety Profile from Efgartigimod Clinical Trials in Participants with Diverse IgG-mediated Autoimmune Diseases	Tuan Vu	Poster Presentation Monday, April 15 11:45 a.m.-12:45 p.m. MT
Long-Term Safety, Tolerability, and Efficacy of Subcutaneous Efgartigimod PH20 in	James Howard	Poster Presentation Wednesday, April 17

Participants With Generalized Myasthenia Gravis: Interim Results of the ADAPT-SC+ Study		11:45 a.m.-12:45 p.m. MT
Fixed-Cycle and Continuous Dosing of Intravenous Efgartigimod for Generalized Myasthenia Gravis: Study Design of ADAPT NXT	Vera Brill	Poster Presentation Wednesday, April 17 11:45 a.m.-12:45 p.m. MT
Achievement of Minimal Symptom Expression and Effect on Disease-Specific Measures in Acetylcholine Receptor Antibody-Positive Participants With Generalized Myasthenia Gravis Treated With Efgartigimod in ADAPT/ADAPT+	Srikanth Muppidi	Poster Presentation Wednesday, April 17 11:45 a.m.-12:45 p.m. MT
Analysis of Serious Infections and Malignancy Risk in Myasthenia Gravis: a US Claims Database Study	Jana Podhorna	Poster Presentation Wednesday, April 17 11:45 a.m.-12:45 p.m. MT

More information on the program is available at AAN.

See Important Safety Information below, full United States Prescribing Information for VYVGART and full Prescribing Information for VYVGART Hytrulo for additional information.

What is VYVGART® (efgartigimod alfa-fcab) for intravenous (IV) infusion and what is VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection?

VYVGART and VYVGART HYTRULO are both prescription medicines, each 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. 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 and VYVGART HYTRULO can cause serious allergic reactions and a decrease in blood pressure leading to fainting

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

Infection

VYVGART and 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 and 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 and 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 or 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 or 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 and 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 and 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 and the full [Prescribing Information](#) for VYVGART HYTRULO.

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,¹ where muscles throughout the body may be affected. Patients with confirmed AChR antibodies account for approximately 85% of the total gMG population.¹

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 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 and China 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 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 and follow us on [LinkedIn](#), [Twitter](#), and [Instagram](#).

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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 “aims,” “committed,” “expects,” “may,” “will,” “strive” or “anticipate” and include statements argenx makes concerning the potential impact of VYVGART and VYVGART Hytrulo for CIDP patients; its promise to transform patients’ lives with innovative treatments; the opportunity with VYVGART and VYVGART Hytrulo to deliver significant value to the gMG patient community by driving consistent and repeatable improvements; its expectation that VYVGART and VYVGART Hytrulo reduce maternal IgG antibody levels, thereby reducing the passive protection to the newborn; 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 development of novel drug therapies, preclinical and clinical trial and product development activities and regulatory approval requirements, the acceptance of our products and product candidates by our patients as safe, effective and cost-effective, and the impact of governmental laws and regulations on our business. 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.