argenx Data Highlight Evidence that VYVGART and VYVGART Hytrulo Drive Transformative Outcomes for Patients with Debilitating Autoimmune Disease

ADHERE data show VYVGART® Hytrulo has potential to be first advancement for CIDP patients in 30 years

Real-world data demonstrate gMG patients able to significantly reduce steroid use over first six months of initiating VYVGART® treatment

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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 that data from its Phase 3 ADHERE trial evaluating VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) in patients with chronic inflammatory demyelinating polyneuropathy (CIDP) were presented for the first time to the medical community during the Clinical Trials Plenary Session at the American Academy of Neurology (AAN) Annual Meeting in Denver, CO.

argenx also highlighted clinical trial and real-world data across seven posters and presentations that continue to reinforce VYVGART and VYVGART Hytrulo as a transformative treatment option for gMG patients.

“Our innovative approach to autoimmunity research is changing expectations for the global immunology community,” said Luc Truyen, M.D., Ph.D., Chief Medical Officer, argenx. “The gMG and CIDP data presented at AAN reinforce that our pioneering approach to transforming autoimmunity is redefining what is possible for patients and their communities.”

“Patients with CIDP face a number of diagnostic and treatment challenges” said Jeffrey Allen, M.D., Professor, Department of Neurology, University of Minnesota and Principal Investigator in the ADHERE trial. “The results of the ADHERE trial show that VYVGART Hytrulo reduces the risk of clinical deterioration in patients with CIDP while minimizing side effects and reducing the treatment burden. These findings enhance our understanding of the role that IgG autoantibodies are likely to play in the disease, and open the door to new safe, effective and well-tolerated treatments that eliminate pathogenic IgGs.”

ADHERE Plenary Session (PL5) Highlights Rapid, Deep and Clinically Meaningful, and Durable Functional Improvements in CIDP

In the ADHERE study, a majority of patients treated with VYVGART Hytrulo, regardless of prior treatment, demonstrated evidence of rapid clinical improvement, and a reduced risk of relapse compared to those treated with placebo. As previously reported, ADHERE met its primary endpoint (p=0.000039) demonstrating a 61% reduction (HR: 0.39 95% CI: 0.25; 0.61) in the risk of relapse versus placebo. VYVGART Hytrulo was well-tolerated, and the observed safety and tolerability profile was consistent with previous clinical trials.

- **Evidence of rapid onset and maintenance of clinical response:** In the open-label Stage A of the ADHERE study, 67% of patients treated with VYVGART Hytrulo demonstrated evidence of clinical improvement (ECI), including 40% who had achieved ECI by the earliest possible measure at week 4. In Stage B, VYVGART Hytrulo-treated patients maintained a clinical response to treatment longer than those on placebo as evidenced by a statistically significant and clinically relevant reduction in risk of relapse. Results across both Stage A and B indicate IgG autoantibodies play a significant role in mediating the underlying biology of CIDP.
- **Deep and clinically meaningful functional improvements**: 81% of VYVGART Hytrulo-treated patients demonstrated ≥1 point improvement on the aINCAT as compared to baseline Stage A scores in ADHERE, which includes 42% of patients with ≥2 point improvement, 28% with ≥3 point improvement, and 12% with ≥4 point improvement.
- **Clinical benefit demonstrated regardless of prior CIDP treatment:** Clinical benefit was seen across all patient subtypes, including those who had previously received corticosteroids, intravenous or subcutaneous immunoglobulin, or were on no treatment prior to study entry.
- **High rate of treatment continuation:** 99% of eligible patients continued to the ADHERE-Plus open-label extension study.
- **FDA decision on CIDP sBLA expected by June 21, 2024**: Data from the ADHERE trial were submitted to the U.S. Food and Drug Administration (FDA) as part of a supplemental Biologics License Application (sBLA) for VYVGART Hytrulo for the treatment of CIDP. The application was accepted for Priority Review in February 2024 and has been granted a PDUFA target action date of June 21, 2024.

AAN presentations highlight rapid, deep, and sustained improvements in gMG with ability to reduce steroid burden

Clinical trial data and real-world evidence presented during AAN continue to highlight the differentiated efficacy and safety profile of VYVGART and VYVGART Hytrulo, driving rapid, deep, and sustained improvement across disease scales and with different dosing schedules, including the ability for patients to achieve minimal symptom expression (MSE).

- MSE results in ADAPT/ADAPT+: Poster Session 10
- ADAPT-SC+ interim results: Poster Session 10
- ADAPT-NXT interim results: Poster Session 10
- Cost-benefit analysis of efgartigimod to IVIG in Canada: Poster Session 4

Side effects from long-term steroid use continue to be a significant burden associated with autoimmune disease, reinforcing the importance of the favorable safety profile of VYVGART. New data presented in an oral presentation (Scientific Platform Session 38) during AAN characterize how VVYGART treatment can significantly reduce concomitant steroid use.

- A substantial proportion of gMG patients (46%) were able to reduce steroid use over the first six months of initiating VYVGART treatment, including 34% of patients who tapered to <5mg/day and 18% who reduced completely to zero.
- Overview of efgartigimod safety profile across indications: Poster Session 4
- Analysis of serious infections and malignancies in MG: Poster Session 10

About ADHERE Trial Design
The ADHERE trial was a multicenter, randomized, double-blind, placebo-controlled trial evaluating VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP). ADHERE enrolled 322 adult patients with CIDP who were treatment naïve (not on active treatment within the past six months or newly diagnosed) or being treated with immunoglobulin therapy or corticosteroids. The trial consisted of an open-label Stage A followed by a randomized, placebo-controlled Stage B. In order to be eligible for the trial, the diagnosis of CIDP was confirmed by an independent panel of experts. Patients entered a run-in stage, where any ongoing CIDP treatment was stopped and in order to be eligible for Stage A had to demonstrate active disease, with clinically meaningful worsening on at least one CIDP clinical assessment tool, including INCAT, I-RODS, or mean grip strength. Treatment naïve patients were able to skip the run-in period with proof of recent worsening. To advance to Stage B, patients needed to demonstrate evidence of clinical improvement (ECI) with VYVGART Hytrulo. ECI was achieved through improvement of the INCAT score, or improvement on I-RODS or mean grip strength if those scales had demonstrated worsening during the run-in period. In Stage B, patients were randomized to either VYVGART Hytrulo or placebo for up to 48 weeks. The primary endpoint was measured once 88 total relapses or events were achieved in Stage B and was based on the hazard ratio for the time to first adjusted INCAT deterioration (i.e. relapse). After Stage B, all patients had the option to roll-over to an open-label extension study to receive VYVGART Hytrulo.

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.

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 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 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," "potential," "likely," or and include statements argenx makes concerning the potential impact of VYVGART and VYVGART Hytrulo for CIDP patients; its pioneering approach to transforming autoimmunity redefining what is possible for patients and their communities; the role IgG autoantibodies are likely to play in the disease, and new safe, effective and well-tolerated treatments that eliminate pathogenic IgGs; and the expected FDA's decision of CIDP sBLA. 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 argenx's products and product candidates by its patients as safe, effective and cost-effective, the impact of governmental laws and regulations on its business, and the results of its PDUFA review. 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.