argenx Highlights Data Evaluating VYVGART in Neuromuscular Autoimmune Disease at AANEM and MGFA Scientific Sessions

Long-term clinical trial and real-world data illustrate VYVGART® *drives consistent, repeatable and clinically meaningful responses, including minimal symptom expression (MSE) in generalized myasthenia gravis (gMG)*

Patients treated with VYVGART experienced consistent improvements on key quality of life measures based on long-term gMG extension data

Data across multiple indications and dosing schedules confirm favorable safety profile and no increase in treatment-emergent adverse event rates with longer exposure

Amsterdam, the Netherlands – Nov. 1, 2023 – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced 20 presentations of clinical trial and real-world data from studies of VYVGART® and VYVGART Hytrulo® (VYVGART) in neuromuscular autoimmune disease. The data presentations will be featured at the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) Annual Meeting and the Myasthenia Gravis Foundation of America (MGFA) Scientific Session, taking place in Phoenix, AZ from November 1-4, 2023.

“As leaders in the field of FcRn inhibition, we continue to generate deep and broad data from our clinical trials, including long-term extension and real-world evidence studies,” said Luc Truyen, M.D., Ph.D., Chief Medical Officer at argenx. "With VYVGART for gMG, we continue to show favorable safety and consistent, repeatable clinically meaningful responses, including the ability of patients to achieve MSE, across three years of treatment. The ADHERE study, the largest in the history of CIDP, further demonstrates our commitment to the neuromuscular community. These data characterize the broad impact our first-in-class FcRn blocker can have on the lives of people living with CIDP, and our work to establish its safety and efficacy in the treatment of CIDP represents an exciting step forward for this community.”

Highlights from Data Presented at AANEM and MGFA

- **Consistent, Repeatable Responses**: Long-term clinical data from ADAPT+ and ADAPT-SC+ and real-world data illustrate the ability of VYVGART to provide consistent, repeatable, and clinically meaningful responses across more than 19 cycles, including improvements in quality-of-life measures, for anti-acetylcholine receptor (AChR) antibody positive patients with gMG.
- **Achievement of Minimal Symptom Expression**: Treatment with VYVGART resulted in 40.5% - 44.6% of patients achieving MSE in ADAPT and ADAPT+. Patients achieving MSE reported quality of life measures comparable to healthy populations. Similar results were demonstrated in ADAPT-SC+ with 35.5%-40.7% of patients achieving MSE following treatment with VYVGART Hytrulo.
- **ADHERE Results**: Positive topline results from the ADHERE study of VYVGART Hytrulo in chronic inflammatory demyelinating polyneuropathy (CIDP) were first reported in July 2023 and are being presented again during the conference. The full dataset from ADHERE will be presented at a medical meeting in 2024.
- **Vaccine Response:** Study participants were able to mount effective humoral immune responses to polyvalent pneumococcal vaccine regardless of whether administered during or after VYVGART administration.
- **Seronegative Population:** Long-term treatment with VYVGART Hytrulo was associated with consistent and repeatable improvements on MG-ADL and MG-QoL15r scales in seronegative (anti-AChR antibody negative) gMG patients.
- **Favorable Safety Profile:** VYVGART shows consistency of safety across multiple indications with TEAE rates that were comparable to placebo, mostly mild to moderate in severity and did not increase with longer exposure.

Additional data are being presented from case studies of gMG patients with LRP4 antibodies, a meta-analysis of quality-of-life outcomes of VYVGART and other gMG treatments, and argenx-sponsored health economic outcomes research studies demonstrating gMG patients facing social-determinants of health challenges experience health inequities related to increased utilization of acute care facilities, and delayed diagnosis and access to treatment.

AANEM Poster Presentations (November 1-4, 2023)

#	Title	Lead Author	Presentation
143	Efficacy, Safety, And Tolerability Of Efgartigimod In Patients With Chronic Inflammatory Demyelinating Polyneuropathy: Results From The Adhere Trial	Richard Lewis, MD	**Poster Session I** Nov. 2 6:00 PM - 6:30 PM MST **Poster Session II** Nov. 3 9:30 AM - 10:00 AM MST
151	Long-Term Safety, Tolerability, and Efficacy of Subcutaneous Efgartigimod PH20 in	James F.	**Poster Session**

	Participants With Generalized Myasthenia Gravis: Interim Analysis of Anti-Acetylcholine Receptor Autoantibody Seronegative Participants in the ADAPT-SC+ Study	Howard Jr., MD	**I** Nov. 2 6:00 PM - 6:30 PM MST **Poster Session III** Nov. 3 3:00 PM - 3:30 PM MST
270	Dose Selection and Clinical Development Of Efgartigimod PH20 Subcutaneous In Patients With Generalized Myasthenia Gravis	Tuan Vu, MD	**Poster Session I** Nov. 2 6:00 PM - 6:30 PM MST **Poster Session II** Nov. 3 9:30 AM - 10:00 AM MST
222	Long-Term Safety, Tolerability, and Efficacy of Subcutaneous Efgartigimod PH20 in Patients With Generalized Myasthenia Gravis: Interim Results of the ADAPT-SC+ Study	Yuebing Li, MD, PhD	**Poster Session I** Nov. 2 6:00 PM - 6:30 PM MST **Poster Session III** Nov. 3 3:00 PM - 3:30 PM MST
152	Long-Term Safety, Tolerability, and Efficacy of Efgartigimod in Patients With Generalized Myasthenia Gravis: Concluding Analyses From the ADAPT+ Study	James F. Howard Jr., MD	**Poster Session I** Nov. 2 6:00 PM - 6:30 PM MST **Poster Session III** Nov. 3 3:00 PM - 3:30 PM MST
240	A Case of Treatment With Efgartigimod in a Patient With Generalized Myasthenia Gravis and LRP4 Antibodies	Eduardo De Sousa, MD	**Poster Session I** Nov. 2 6:00 PM - 6:30 PM MST **Poster Session II** Nov. 3 9:30 AM - 10:00 AM MST
220	Overview Of The Safety Profile From Efgartigimod Clinical Trials In Participants With Diverse Immunoglobulin G-Mediated Autoimmune Diseases	Kelly Gwathmey, MD	**Poster Session I** Nov. 2 6:00 PM - 6:30 PM MST

			Poster Session III Nov. 3 3:00 PM - 3:30 PM MST
139	Treatment-Related Inequities in Patients With Generalized Myasthenia Gravis Facing Social Determinants of Health Challenges: A Survey of Neurologists in the United States	A. Gordon Smith, MD	**Poster Session I** Nov. 2 6:00 PM - 6:30 PM MST **Poster Session III** Nov. 3 3:00 PM - 3:30 PM MST
138	Diagnosis Inequities In Patients With Generalized Myasthenia Gravis Facing Social Determinants Of Health Challenges: A Survey Of Neurologists In The United States	A. Gordon Smith, MD	**Poster Session I** Nov. 2 6:00 PM - 6:30 PM MST **Poster Session III** Nov. 3 3:00 PM - 3:30 PM MST

MGFA Oral and Poster Presentations (November 1, 2023)

Title	Lead Author	Presentation
Achievement of Minimal Symptom Expression in Acetylcholine-Receptor Antibody-Positive Participants with Generalized Myasthenia Gravis and Effect on Disease-Specific Measures in ADAPT/ADAPT+ Studies	James F. Howard, MD	**Oral Presentation** 10:07 AM - 10:14 AM MST
Subcutaneous Efgartigimod PH20 Treatment in Participants With Generalized Myasthenia Gravis in ADAPT-SC+: Interim Analyses on Quality of Life, Efficacy, Tolerability, and Long-Term Safety	Tuan Vu, MD	**Oral Presentation** 10:42 AM – 10:49 AM MST
Racial Disparities in Acute Care Utilization Outcomes Among Those with Myasthenia Gravis	Pushpa Narayanaswami, MD	**Oral Presentation** 9:07 AM - 9:14 AM MST
Humoral Immune Response to Polyvalent Pneumococcal Vaccine in Healthy Participants Receiving Efgartigimod	Antoine Azar, MD	**Poster Session** 9:35 AM - 10:05 AM MST
Network Meta Analysis of Treatment Options in Generalized Myasthenia Gravis: Impact on Health-Related Quality of Life	Gil Wolfe, MD	**Poster Session** 9:35 AM - 10:05 AM MST
Overview of the Safety Profile From Efgartigimod Clinical Trials in Participants with Diverse IgG-mediated Autoimmune Diseases	Kelly Gwathmey, MD	**Poster Session** 9:35 AM - 10:05 AM MST
Treatment-Related Inequities in Patients With Generalized Myasthenia Gravis Facing Social Determinants of Health Challenges: A Survey of Neurologists in the United States	A. Gordon Smith, MD	**Poster Session** 9:35 AM - 10:05 AM MST
Diagnostic Inequities in Patients With Generalized Myasthenia Gravis Facing Social Determinants of Health Challenges: A Survey of Neurologists in the United States	A. Gordon Smith, MD	**Poster Session** 9:35 AM - 10:05 AM MST
Real-World Burden Associated With Social Determinants of Health Challenges For Individuals Living with Generalized Myasthenia Gravis in the United States	Tom Hughes	**Poster Session** 9:35 AM - 10:05

		AM MST
Real-World Outcomes of Patients living with Generalized Myasthenia Gravis Initiating Efgartigimod treatment in the United States	Cynthia Qi	**Poster Session** 9:35 AM - 10:05 AM MST
Association between patient support program participation and access to efgartigimod treatment for generalized myasthenia gravis	Glenn Phillips	**Poster Session** 9:35 AM - 10:05 AM MST

More information on the programs are available at AANEM and MGFA.

See Important Safety Information below and full Prescribing Information for VYVGART Hytrulo for additional information

Important Safety Information

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).

IMPORTANT SAFETY INFORMATION

Infection
VYVGART and VYVGART HYTRULO may increase the risk of infection. The most common infections observed in Study 1 were urinary tract infection (10% of efgartigimod alfa-fcab-treated patients vs 5% of placebo-treated patients) and respiratory tract infection (33% of efgartigimod alfa-fcab-treated patients vs 29% of placebo-treated patients). Patients on efgartigimod alfa-fcab vs placebo had below normal levels for white blood cell counts (12% vs 5%, respectively), lymphocyte counts (28% vs 19%, respectively), and neutrophil counts (13% vs 6%, respectively). The majority of infections and hematologic abnormalities were mild to moderate in severity. Delay the administration of VYVGART or VYVGART HYTRULO in patients with an active infection until the infection has resolved; monitor for clinical signs and symptoms of infections. If serious infection occurs, administer appropriate treatment and consider withholding treatment with VYVGART or VYVGART HYTRULO until the infection has resolved.

Immunization
Immunization with vaccines during treatment with VYVGART or VYVGART HYTRULO has not been studied; the safety with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because VYVGART and VYVGART HYTRULO cause a reduction in immunoglobulin G (IgG) levels, vaccination with live-attenuated or live vaccines is not recommended during treatment with VYVGART or VYVGART HYTRULO. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with VYVGART or

VYVGART HYTRULO.

Hypersensitivity Reactions
Hypersensitivity reactions, including rash, angioedema, and dyspnea were observed in patients treated with VYVGART or VYVGART HYTRULO. Urticaria was also observed in patients treated with VYVGART HYTRULO. In clinical trials, hypersensitivity reactions were mild or moderate, occurred within 1 hour to 3 weeks of administration, and did not lead to treatment discontinuation. Monitor patients during and for one hour after VYVGART administration, or for at least 30 minutes after VYVGART HYTRULO administration, for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs during VYVGART or VYVGART HYTRULO administration, discontinue use and institute appropriate supportive measures if needed.

ADVERSE REACTIONS
In Study 1, the most common (≥10%) adverse reactions in efgartigimod alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. In Study 2, the most common (≥10%) adverse reactions in VYVGART HYTRULO-treated patients were injection site reactions and headache. Injection site reactions occurred in 38% of VYVGART HYTRULO-treated patients, including injection site rash, erythema, pruritus, bruising, pain, and urticaria. In Study 2 and its open-label extension, all injection site reactions were mild to moderate in severity and did not lead to treatment discontinuation. The majority occurred within 24 hours after administration and resolved spontaneously. Most injection site reactions occurred during the first treatment cycle, and the incidence decreased with each subsequent cycle.

USE IN SPECIFIC POPULATIONS
Pregnancy
As VYVGART and VYVGART HYTRULO are expected to reduce maternal IgG antibody levels, reduction in passive protection to the newborn is anticipated. Risks and benefits should be considered prior to administering live or live attenuated vaccines to infants exposed to VYVGART or VYVGART HYTRULO in utero.

Lactation
There is no information regarding the presence of efgartigimod alfa-fcab from administration of VYVGART, or efgartigimod alfa or hyaluronidase from administration of VYVGART HYTRULO, in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VYVGART or VYVGART HYTRULO, and any potential adverse effects on the breastfed infant from VYVGART or VYVGART HYTRULO or from the underlying maternal condition.

INDICATION

VYVGART® (efgartigimod alfa-fcab) for intravenous infusion and VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection are each indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

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 (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 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.

References

[1] 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 Statement

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 "believes," "hope," "estimates," "anticipates," "expects," "intends," "may," "will," or "should" and include statements argenx makes concerning the expected consistency, safety, tolerability, efficacy and quality-of-life benefits of VYVGART for patients with gMG and CIDP; VYVGART's potential to achieve MSE for patients; and argenx's planned future presentations of additional study data. 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. 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.