argenx to Highlight Key Programs from Neuromuscular Franchise at Upcoming Medical Meetings

Scientific presentations demonstrate argenx's leadership in FcRn blockade and commitment to innovating for patients across multiple neuromuscular diseases

Additional data from ADAPT+ open-label study support long-term safety of VYVGART® (efgartigimod alfa-fcab) for treatment of adult patients with generalized myasthenia gravis (gMG), who experienced consistent improvements in function and strength over multiple years

Pooled data from ADAPT studies and real-world clinical setting suggest VYVGART treatment was associated with clinically meaningful disease score improvements in seronegative gMG patients

Amsterdam, the Netherlands – **September 21, 2022** 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 from its neuromuscular franchise at the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) Annual Meeting (September 21-24, 2022) and the Myasthenia Gravis Foundation of America (MGFA) Scientific Session (September 21, 2022), both being held in Nashville, TN.

"We made a long-term commitment to the gMG community to reach as many people as possible who are living with this devastating disease, providing them with a new standard in treatment. The data we are presenting this week further underscore this commitment with a growing body of clinical safety and efficacy data on VYVGART, our first-in-class FcRn blocker and the anchor of our neuromuscular franchise. gMG is a disease that affects each patient differently and that is exactly how we want to approach treatment – meeting the needs of patients and physicians based on their individual disease experience," said Tim Van Hauwermeiren, Chief Executive Officer, argenx. "Deeper within our neuromuscular franchise, we are highlighting the thoughtful trial designs of the ADHERE study of efgartigimod in CIDP and the ARDA trial of ARGX-117 in MMN, bringing us one step closer to reaching many more people suffering from severe autoimmune diseases."

Highlights from AANEM and MGFA

Seventeen scientific abstracts have been accepted between both meetings, including previously reported data from the ADAPT+ open-label extension study evaluating the long-term safety, tolerability and efficacy of VYVGART and the registrational ADAPT-SC trial evaluating the noninferiority of subcutaneous (SC) efgartigimod compared to intravenously administered VYVGART based on total IgG reduction. New data analyses from ADAPT+ and real-world case studies are being presented on the adult anti-acetylcholine receptor antibody negative (AChR-Ab-) gMG patient population.

- **ADAPT+**: Data suggest that long-term treatment with VYVGART provides consistent decreases in IgG antibodies and repeatable improvements in function and strength based on Myasthenia Gravis Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) disease scores; the long-term safety profile of VYVGART remained consistent with the Phase 3 ADAPT trial.
- **ADAPT-SC**: Topline data show SC efgartigimod was noninferior to VYVGART in total IgG reduction at day 29 and demonstrated consistent clinical improvement based on MG-ADL and QMG disease scores.
- **Seronegative gMG Population:** New pooled data from ADAPT+ and real-world case studies indicate that VYVGART treatment was associated with clinically meaningful disease score improvements (≥2-point improvement in MG-ADL and ≥3-point improvement in QMG) in adult AChR-Ab- gMG patients. Clinically meaningful improvement in MG-ADL scores was observed in AChR-Ab- patients across 10 treatment cycles in ADAPT+. Additionally, preliminary real-world experience in the AChR-Ab- patient population is largely consistent with the ADAPT studies.
- **gMG Disease and Treatment Burden**: Additional evidence from argenx-sponsored health economic outcomes research studies demonstrate the severity of gMG based on annual hospitalizations and readmission and mortality rates, especially in older gMG patients.
- **Vaccine Response**: Preliminary data suggest treatment with VYVGART does not impact immune response to vaccinations, including to COVID-19.

AANEM Poster Presentations are taking place at the following times in Ryman Exhibit Hall B1:

AANEM Session I: Thursday, 9/22 from 6:00 - 6:30 pm CT
AANEM Session II: Friday, 9/23 from 9:30 - 10:00 am CT
AANEM Session III: Friday, 9/23 from 3:30 - 4:00 pm CT

VYVGART® (efgartigimod alfa-fcab)

Long-Term Safety, Tolerability, and Efficacy of Efgartigimod in Patients with Generalized Myasthenia Gravis: Interim Results of the ADAPT+ Study

- James F. Howard Jr., M.D.
- Session I and III

Response to Coronavirus 2019 Vaccination in Patients Receiving Efgartigimod

- James F. Howard Jr., M.D.
- Session I and II

Continuous and Fixed-Cycle Dosing of Intravenous Efgartigimod for Generalized Myasthenia Gravis: Study Design of ADAPT-NXT

- Kelly Gwathmey, M.D.
- Session I and II

Study Design of Intravenous Efgartigimod in Juvenile Generalized Myasthenia Gravis

- Nancy L. Kuntz, M.D.
- Session I and III

The Effect of Obesity on Efficacy and Safety in the ADAPT Trial of Efgartigimod for Generalized Myasthenia Gravis

- Michael Pulley, M.D., Ph.D.
- Session I and II

Efficacy, Safety, And Tolerability of Efgartigimod in Anti-Acetylcholine Receptor Autoantibody Seronegative Patients with Generalized Myasthenia Gravis: Integrated Interim Analysis of ADAPT and ADAPT+ Studies

- Tuan Vu, M.D.
- Session I and II

Effects of Efgartigimod Treatment on Humoral and Cellular Immune Responses: Analysis of T-Cell-Dependent Antibody Response in Cynomolgus Monkeys

- Deborah Gelinas, M.D., argenx
- Session I and II

Safety and Tolerability of Efgartigimod in Patients with Generalized Myasthenia Gravis: Integrated Interim Analysis of Infection Risk and Hematological Changes

- Srikanth Muppidi, M.D.
- Session I and II

Diagnostic Adjudication of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) in the ADHERE Trial: Updates on the First 200 Cases

- Richard A. Lewis, M.D.
- Session I and III

ARGX-117 (anti-C2 monoclonal antibody)

Safety, Efficacy, and Pharmacokinetics of ARGX-117 in Adults with Multifocal Motor Neuropathy: A Global, Multicenter, Placebo Controlled Phase 2 Study (ARDA)

- Olivier van de Steen, M.D., argenx
- Session I and III

MGFA Presentations are taking place at the following times in Tennessee Ballroom AB:

Oral Presentation: A Pharmacodynamic Noninferiority Study Comparing Subcutaneous Injections of Efgartigimod Ph20 with Intravenous Infusions of Efgartigimod: Results of the Phase 3 ADAPT-SC Study

- James F. Howard Jr., M.D.
- September 21; 9:02am ET

Oral Presentation: Efficacy of Efgartigimod Treatment in Patients With Anti-Acetylcholine Receptor Antibody Negative Myasthenia Gravis: Clinical Trial and Real-World Data

- Tania Beltran Papsdorf, M.D.
- September 21, Time: 10:57am ET

Oral Presentation: A Phase 3b Open-Label Study to Further Individualize Efgartigimod Treatment Options for Patients with Generalized Myasthenia Gravis

- Kelly Gwathmey, M.D.
- September 21, Time: 11:35am ET

Oral Presentation: Risk Benefit Analysis of Treatments for Patients with Myasthenia Gravis

- Gordon Smith, M.D., FAAN
- September 21, 11:40am ET

Poster Presentation: Efgartigimod Demonstrates Consistent Improvements in Generalized Myasthenia Gravis Across Patient Subgroups, Including Early in Diagnosis

- Vera Bril, M.D.
- September 21, 8:00 am – 12:00 pm ET

Poster Presentation: Real-World Treatment Patterns in Adults with Generalized Myasthenia Gravis Initiating Intravenous Immunoglobulin in the United States

- Cynthia Qi, argenx
- September 21, 8:00 am – 12:00 pm ET

Poster Presentation: Trends in Hospital Admissions and Readmissions for Patients with MG from U.S. National Research Databases

- Glenn Phillips, Ph.D., argenx
- September 21, 8:00 am – 12:00 pm ET

See the full Prescribing Information for VYVGART in the U.S., which includes the below Important Safety Information. For more information related to VYVGART in Japan, visit argenx.jp.

Important Safety Information for VYVGART® (efgartigimod alfa-fcab) intravenous (IV) formulation (U.S. prescribing 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).
What is the most important information I should know about VYVGART?
VYVGART may cause serious side effects, including:

- **Infection.** VYVGART may increase the risk of infection. In a clinical study, the most common infections were urinary tract and respiratory tract infections. More patients on VYVGART vs placebo had below normal levels for white blood cell counts, lymphocyte counts, and neutrophil counts. The majority of infections and blood side effects were mild to moderate in severity. Your health care provider should check you for infections before starting treatment, during treatment, and after treatment with VYVGART. Tell your health care provider if you have any history of infections. Tell your health care provider right away if you have signs or symptoms of an infection during treatment with VYVGART such as 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.
- **Undesirable immune reactions (hypersensitivity reactions).** VYVGART can cause the immune system to have undesirable reactions such as rashes, swelling under the skin, and shortness of breath. In clinical studies, the reactions were mild or moderate and occurred within 1 hour to 3 weeks of administration, and the reactions did not lead to VYVGART discontinuation. Your health care provider should monitor you during and after treatment and discontinue VYVGART if needed. Tell your health care provider immediately about any undesirable reactions.

Before taking VYVGART, tell your health care provider about all of your medical conditions, including if you:

- Have a history of infection or you think you have an infection.
- Have received or are scheduled to receive a vaccine (immunization). Discuss with your health care provider whether you need to receive age-appropriate immunizations before initiation of a new treatment cycle with VYVGART. The use of vaccines during VYVGART treatment has not been studied, and the safety with live or live-attenuated vaccines is unknown. Administration of live or live-attenuated vaccines is not recommended during treatment with VYVGART.
- Are pregnant or plan to become pregnant and are breastfeeding or plan to breastfeed.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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 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 Multifocal Motor Neuropathy
Multifocal motor neuropathy (MMN) is a rare chronic, inflammatory, pure motor polyneuropathy leading to slowly progressive muscle weakness, mainly of the hands and forearms and lower legs. MMN is associated with increased levels of immunoglobulin M (IgM) autoantibodies against the ganglioside GM1, which is widely expressed in the nervous system and important for nerve conduction. The clinical course of MMN is chronically progressive without remission. MMN is often misdiagnosed as CIDP because of the similar clinical features and its progressive nature but MMN is asymmetric and affects the right and left side of the body differently.

About VYVGART

VYVGART (efgartigimod alfa-fcab) is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating immunoglobulin G (IgG) autoantibodies. It is the first and only approved FcRn blocker. VYVGART is approved in the United States and Europe 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). VYVGART is not currently approved in any country for CIDP or MMN, and clinical studies of these conditions are ongoing.

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-and-only approved neonatal Fc receptor (FcRn) blocker in the U.S., Japan, and the EU. 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 "believes," "hope," "estimates," "anticipates," "expects," "intends," "may," "will," or "should" and include statements argenx makes concerning the long-term efficacy, safety and tolerability of VYVGART® (efgartigimod alfa-fcab) for treatment of adult patients with generalized myasthenia gravis (gMG) and the safety, efficacy, and pharmacokinetics of ARGX-117 in adults with multifocal motor neuropathy. 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 publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.

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[1] Behin et al. New Pathways and Therapeutics Targets in Autoimmune Myasthenia Gravis. J Neuromusc Dis 5. 2018. 265-277