argenx Presents Interim Results from ADAPT+ Open-Label Extension Study Evaluating VYVGART® (efgartigimod alfa-fcab) in Generalized Myasthenia Gravis at 2022 AAN Annual Meeting

Interim data suggest long-term treatment with VYVGART provides improvement in generalized myasthenia gravis (gMG) disease scores that remains consistent over multiple treatment cycles

Long-term safety profile of VYVGART treatment consistent with Phase 3 ADAPT study

VYVGART is the first-and-only approved neonatal Fc receptor (FcRn) blocker

Breda, the Netherlands—April 5, 2022—argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced interim results from ADAPT+, an ongoing Phase 3, open-label, three-year extension study evaluating long-term safety, tolerability and efficacy of VYVGART® (efgartigimod alfa-fcab) for the treatment of adults with gMG. The data will be presented today in an oral presentation at the 74th Annual Meeting of the American Academy of Neurology (AAN).

"gMG can have a devastating impact on a person and their ability to lead a fulfilling life. For healthcare providers treating gMG patients, the ADAPT+ results provide greater understanding of how long-term treatment with VYVGART could help their patients overcome some of the daily limitations they face living with this debilitating disease," said James F. Howard Jr., M.D., Professor of Neurology, Medicine and Allied Health, Department of Neurology, UNC School of Medicine and principal investigator for the ADAPT+ trial. "Patients who participated in ADAPT+ continued to experience consistent efficacy and safety over a year of treatment, reinforcing the potential benefit this targeted therapy can offer to this community."

"The ADAPT+ data continue to strengthen our belief in the potential of VYVGART to improve the lives of people impacted by gMG," said Luc Truyen, M.D., Ph.D., Chief Medical Officer of argenx. "Together with the robust clinical data already observed in the ADAPT study, these results further support the value of VYVGART as an efficacious, well-tolerated targeted treatment option for a patient community that has been underserved for years. We are grateful for and humbled by the ongoing participation of patients, caregivers, and investigators in the clinical trial, all of whom make continued innovation possible."

Highlights of ADAPT+ Interim Analysis

139 patients received at least one dose of VYVGART in ADAPT+. As of the interim analysis, the mean treatment duration was 363 days. Efficacy analyses were based on 106 patients who are anti-acetylcholine receptor (AChR) antibody positive.

Patients who continued on long-term treatment with VYVGART experienced consistent and clinically meaningful improvement on both the Myasthenia Gravis Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scales. The safety profile of long-term treatment (up to 10 treatment cycles) with VYVGART continued to be favorable and consistent with ADAPT.

- **Efficacy is repeatable, consistent and predictable with each subsequent treatment cycle**
    - Onset and durability of response remain consistent with each additional treatment cycle
    - Mean improvements on MG-ADL and QMG scales from five treatment cycles were 5.1 and 4.7, respectively, and remained consistent between cycles
    - Depth of response at increasing MG-ADL and QMG response thresholds remains consistent with ADAPT and between ADAPT+ treatment cycles

- 54.6% of patients received ≤5.5 treatment cycles per year based on patients who completed at least one year of VYVGART treatment at time of interim analysis

- **Safety profile consistent with ADAPT**
  - VYVGART was well-tolerated with a consistent safety profile to the ADAPT trial and during the COVID-19 global pandemic. Majority of adverse events were mild to moderate in severity.

Details of AAN oral presentation:
Long-term Safety, Tolerability, and Efficacy of Efgartigimod in Patients with Generalized Myasthenia Gravis: Interim Results of the ADAPT+ Study
Tuesday, April 5, 2022, at 4:06 PM PT
Session: S25: Autoimmune Neurology 2: Clinical Trials and Treatment; Presentation 004
Presenter: James F. Howard Jr., M.D., Professor of Neurology (Neuromuscular Disease), Medicine and Allied Health, Department of Neurology, The University of North Carolina at Chapel Hill School of Medicine

Phase 3 ADAPT+ Study Design
The Phase 3 ADAPT+ trial is a long-term, single-arm, open-label, multicenter trial evaluating the efficacy and safety of VYVGART in patients with gMG. Ninety-one percent (151/167) of ADAPT patients entered the ADAPT+ study. A total of 106 AChR-Ab+ and 33 AChR-Ab– had received at least one dose of open-label VYVGART (including 66 ADAPT placebo patients). The remaining patients were either still responding to treatment from their last cycle in ADAPT, or dropped out between rollover. There were at least four weeks between cycles in the ADAPT+ study, with a maximum of ten cycles. The mean study duration was 363 days, resulting in 138 patient-years of observation.

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 immunoglobulin G (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 Efgartigimod
Efgartigimod is an antibody fragment designed to reduce pathogenic immunoglobulin G (IgG) antibodies by binding to the neonatal Fc receptor and blocking the IgG recycling process. Efgartigimod is being investigated in several autoimmune diseases known to be mediated by disease-causing IgG antibodies, including neuromuscular disorders, blood disorders, and skin blistering diseases.

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 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 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. and Japan. 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

For further information, please contact:
Media:
Kelsey Kirk
kkirk@argenx.com

Investors:
Beth DelGiacco
bdelgiacco@argenx.com

Michelle Greenblatt
mgreenblatt@argenx.com

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 expected long-term safety, tolerability and efficacy of VYVGART® (efgartigimod alfa-fcab) in adult patients with generalized myasthenia gravis. 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.

###