argenx Announces Positive Topline Phase 3 Data from ADAPT-SC Study Evaluating Subcutaneous Efgartigimod for Generalized Myasthenia Gravis

March 23, 2022

- *Study met primary endpoint, demonstrating noninferior total IgG reduction at day 29 with subcutaneously administered efgartigimod compared to intravenous (IV) administration*
- *Secondary endpoints show clinical improvement consistent with IV administration*
- *Biologics License Application (BLA) on track to be submitted to U.S. Food and Drug Administration (FDA) by end of 2022*
- *argenx to host investor call today at 8:30am ET / 1:30pm CET*

Breda, the Netherlands – March 22, 2022 – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced positive topline data from the Phase 3 ADAPT-SC study evaluating subcutaneous (SC) efgartigimod (1000mg efgartigimod-PH20) for the treatment of generalized myasthenia gravis (gMG). SC efgartigimod achieved the primary endpoint of total IgG reduction from baseline at day 29, demonstrating statistical noninferiority to VYVGART® (efgartigimod alfa-fcab) intravenous (IV) formulation in gMG patients. Based on these results, argenx plans to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) by the end of 2022.

SC efgartigimod is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology. ENHANZE facilitates subcutaneous injection delivery of biologics that are typically administered via infusion, providing additional treatment options to patients based on individual preferences.

“Every person living with gMG experiences the disease in their own way, including how they manage symptoms,” said 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 and Principal Investigator for the ADAPT-SC trial. “For many years, patients lacked sufficient treatment options, let alone those that were tailored to their unique needs. These data, along with the recent approval of the intravenous formulation, VYVGART, represent exciting advancements in the management of this debilitating, unpredictable disease by offering patients and physicians the option to select treatment based on individual needs and preferences.”

“Our goal is to redefine and deliver targeted treatment options for people living with gMG globally. By listening to the gMG community, we heard the importance of creating optionality and flexibility for patients. The ADAPT-SC results mark another important step toward achieving this, and further support our vision of delivering a broad array of treatment options for gMG,” said Tim Van Hauwermeiren, Chief Executive Officer of argenx. “We’re excited about the potential to deliver two best-in-class options that provide flexibility around route of administration and dosing schedule, and look forward to collaborating with the FDA to bring another innovative treatment option to people living with gMG.”

Highlights of Topline ADAPT-SC Data

- Primary endpoint of noninferiority was met ($p < 0.0001$); SC efgartigimod demonstrated mean total IgG reduction of 66.4% from baseline at day 29, compared to 62.2% with VYVGART. Results were consistent across the overall population, including those with acetylcholine receptor (AChR) antibodies and patients where AChR antibodies were not detected.
- Additional key secondary endpoints were met, consistent with clinical efficacy results seen in the VYVGART Phase 3 ADAPT study, including:
    - 69.1% of patients treated with SC efgartigimod were responders on the Myasthenia Gravis Activities of Daily Living (MG-ADL) score. Responders are defined as having at least a two-point improvement on the MG-ADL score for at least four consecutive weeks.
    - 65.5% of treated patients were responders on the Quantitative Myasthenia Gravis (QMG) score. Responders are defined as having at least a three-point improvement on the QMG score for at least four consecutive weeks.
- Onset of effect and minimal symptom expression (defined as MG-ADL score of 0 or 1) were also consistent with ADAPT.
- SC efgartigimod demonstrated a safety profile consistent with the Phase 3 ADAPT study. It was generally well-tolerated; the most frequent adverse event being injection site reactions (ISRs), commonly observed with biologics administered subcutaneously. All ISRs were mild to moderate and resolved over time.

Detailed data from the ADAPT-SC trial will be submitted for presentation at a future medical meeting.

Phase 3 ADAPT-SC Trial Design

The Phase 3 ADAPT-SC trial was a randomized, open-label, parallel-group, multicenter trial evaluating the noninferiority of the pharmacodynamic (PD) effect of SC efgartigimod (1000mg efgartigimod-PH20) as compared with IV efgartigimod (10mg/kg) in patients with gMG. The pharmacodynamic effect as measured by percent change from baseline in total IgG levels at day 29, one week after the last dose of IV or SC efgartigimod, served as the

primary endpoint in the ADAPT-SC trial. The correlation between total IgG reduction and clinical benefit in gMG was demonstrated in a Phase 2 and the Phase 3 ADAPT trial, which served as the basis for approval of VYVGART in the U.S. and Japan. Safety, clinical efficacy, immunogenicity and pharmacokinetics (PK) were also assessed.

A total of 110 adult patients with gMG in North America, Europe and Japan enrolled in the ADAPT-SC trial and were treated. Inclusion criteria of the trial were the same as the Phase 3 ADAPT trial of VYVGART; enrolled patients had a confirmed gMG diagnosis and an MG-ADL total score of at least 5 with greater than 50% of the total score attributed to non-ocular symptoms, at screening and baseline. Patients were on a stable dose of at least one gMG treatment prior to randomization, including acetylcholinesterase inhibitors, corticosteroids or nonsteroidal immunosuppressive drugs, and were required to remain on that stable dose throughout the primary trial.

Patients were randomized in a 1:1 ratio to receive SC efgartigimod or IV efgartigimod for one treatment cycle consisting of four doses at weekly intervals. The total study duration was approximately 12 weeks, including seven weeks of follow-up after the treatment cycle.

Conference Call and Webcast

A webcast of the live call may be accessed on the Investors section of the argenx website at argenx.com/investors. A replay of the webcast will be available on the argenx website for approximately one year following the call.

Dial-in numbers:

Please dial in 15 minutes prior to the live call.

Belgium	32 800 50 201
France	33 800 943355
Netherlands	31 20 795 1090
United Kingdom	44 800 358 0970
United States	1 888 415 4250
Japan	81 3 4578 9752
Switzerland	41 43 210 11 32

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

MG is a rare and chronic autoimmune disease where IgG antibodies disrupt communication between nerves and muscles, causing debilitating and potentially life-threatening muscle weakness. More than 85% of people with MG progress to generalized MG (gMG) within 18 months, where muscles throughout the body may be affected, resulting in extreme fatigue and difficulties with facial expression, speech, swallowing and mobility. In more life-threatening cases, MG can affect the muscles responsible for breathing. Patients with confirmed AChR antibodies account for 80-90% of the total gMG population.

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, in both an intravenous and subcutaneous (SC) formulation. SC efgartigimod is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology.

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.

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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," "estimates," "anticipates," "expects," "intends," "may," "will" or "should" and include statements argenx makes concerning the expected benefits of subcutaneous (SC) efgartigimod (1000mg efgartigimod-PH20) for the treatment of generalized myasthenia gravis (gMG) and the market acceptance thereof. 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.