



argenx Demonstrates Commitment to Redefining Treatment Goals for Generalized Myasthenia Gravis with Multiple Presentations at American Academy of Neurology 2023 Annual Meeting

Amsterdam, the Netherlands – [04/18/2023] argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced that it will present six abstracts further demonstrating its long-term commitment to the generalized myasthenia gravis (gMG) community during the 75th American Academy of Neurology (AAN) Annual Meeting, which is taking place from April 22-27, 2023 in Boston, MA. The presentations include clinical and real-world efgartigimod data that demonstrate the potential of neonatal Fc receptor (FcRn) blockade in transforming treatment for gMG and other IgG-mediated autoimmune diseases.

“Our presentations at AAN will showcase the depth of evidence we are generating in support of the clinical and real-world profile of efgartigimod to address the often-underappreciated needs of people living with gMG,” said Luc Truyen, M.D. Ph.D., Chief Medical Officer, argenx. “We have a unique opportunity to recalibrate expectations for patients and their supporters by setting a new standard for what ‘well-controlled’ means in gMG and across autoimmunity more broadly.”

Power of Individualized Dosing from Long-term Extension Studies

The presentations include results from the open-label extension studies of VYVGART® (efgartigimod alfa-fcab) and subcutaneous (SC) efgartigimod following long-term treatment in ADAPT+ (217.5 patient-years follow-up) and ADAPT-SC+ (72 patient-years follow-up). Long-term treatment, administered in individualized dosing cycles, led to consistent and repeatable reductions in IgG antibody levels and improved clinical outcomes.

A cross-indication review of the safety profile of efgartigimod will also be presented across multiple IgG-mediated autoimmune diseases, reinforcing the consistent safety profile observed with efgartigimod.

Potential in Patients Early in gMG Disease Course

A new exploratory analysis will be presented from the ADAPT Phase 3 trial showing that a greater percentage of gMG patients with fewer than three years disease duration were responders and achieved minimum symptom expression (MSE) compared with placebo.

New Opportunities with Patient Support Programs

As part of its commitment to address access for gMG patients impacted by social determinants of health challenges, argenx will present quantitative and qualitative research that identified potential opportunities to expand patient support program offerings, including the establishment of an information hotline and symptom tracking app, a patient mentoring program, an innovative giving strategy and broadened awareness campaigns of nurse case manager services.

Details for the poster presentations are as follows:

Title: Long-Term Safety, Tolerability, And Efficacy of Efgartigimod in Patients with Generalized Myasthenia Gravis: Concluding Analyses from the ADAPT+

Session Date & Time: Oral Presentation - Sunday, April 23 at 2:00pm ET

Presenter: Dr. Mamatha Pasnoor

Abstract Number: S5.006

Title: Long-Term Safety, Tolerability, and Efficacy of Subcutaneous Efgartigimod PH20 in Patients with Generalized Myasthenia Gravis: Interim Results of the ADAPT-SC+ Study

Session Date & Time: Poster Session 1, Sunday, April 23, 8-9 am ET

Presenter: Dr. James F. Howard

Abstract Number: P1.5-014

Title: Dose Selection and Clinical Development of Efgartigimod Ph20 Subcutaneous Inpatients With Generalized Myasthenia Gravis

Session Date & Time: Poster Session 1, Sunday, April 23, 8-9 am ET

Presenter: Dr. George Li

Abstract Number: P1.5-017

Title: Overview of the Safety Profile from Efgartigimod Clinical Trials in Participants with Diverse IgG-Mediated Autoimmune Diseases

Session Date & Time: Poster Session 1, Sunday, April 23, 8-9 am ET

Presenter: Dr. Kelly Gwathmey

Abstract Number: P1.5-001

Title: Efgartigimod Demonstrates Consistent Improvements in Generalized Myasthenia Gravis Patients of Shorter Disease Duration

Session Date & Time: Poster Session 1, Sunday, April 23, 8-9 am ET

Presenter: Dr. Vera Bril

Abstract Number: P1.5-015

Title: Patient Support Program Enhancements In Patients Diagnosed With Generalized Myasthenia Gravis Facing Social Determinants of Health Challenges

Session Date & Time: Poster Session 4, Monday, April 24, 8-9 am ET

Presenter: Dr. Tom Hughes

Abstract Number: P4.9-006

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, where muscles throughout the body may be affected. Patients with confirmed AChR antibodies account for approximately 85% of the total gMG population.

About VYVGART® (efgartigimod alfa-fcab)

VYVGART 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 being studied in adults with primary immune thrombocytopenia (ITP) and other IgG autoantibody-mediated diseases.

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., the EU and UK, 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](#).

For further information, please contact:

Media:

Erin Murphy
emurphy@argenx.com

Investors:

Beth DelGiacco
bdelgiacco@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 argenx’s long-term commitment to the generalized myasthenia gravis (gMG) community, the potential of neonatal Fc receptor (FcRn) blockade in transforming treatment for gMG and other IgG-mediated autoimmune diseases, the expected long-term safety, tolerability and efficacy of VYVGART® (efgartigimod alfa-fcab) in adult patients with gMG; and potential opportunities to expand patient support program offerings. 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.