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argenx Announces FDA Acceptance of Supplemental Biologics License Application with Priority Review for VYVGART in AChR-Ab Seronegative gMG

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Amsterdam, the Netherlands – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted for priority review a supplemental Biologics License Application (sBLA) for VYVGART® (IV: efgartigimod alfa-fcab) for the treatment of adults with acetylcholine receptor antibody (AChR-Ab) seronegative generalized myasthenia gravis (gMG). The application has been granted a Prescription Drug User Fee Act (PDUFA) target action date of May 10, 2026.

“Patients living with seronegative gMG continue to face limited treatment options and there remains a significant need to meaningfully improve their lives. The FDA’s acceptance of our sBLA with Priority Review status reflects the potential of VYVGART to address this need,” said Luc Truyen, M.D., Ph.D., Chief Medical Officer, argenx. “This development brings us closer to expanding the use of VYVGART in a broad spectrum of patients with myasthenia gravis. We look forward to continuing our dialogue with the FDA as they review our application.”

The sBLA is supported by data from the Phase 3 ADAPT SERON study, which evaluated the efficacy and safety of VYVGART in adults with AChR-Ab seronegative gMG across all three subtypes – MuSK+, LRP4+, and triple seronegative gMG. The study met its primary endpoint (p-value=0.0068), demonstrating a statistically significant improvement in Myasthenia Gravis Activities of Daily Living (MG-ADL) total score compared to placebo after four weeks.

In the overall population, mean change from baseline in patients treated with VYVGART was a clinically meaningful 3.35 point improvement in MG-ADL total score at week 4. Improvements in MG-ADL and Quantitative Myasthenia Gravis (QMG) scores were observed across subsequent

treatment cycles in the overall population and in all patient subgroups, including MuSK+, LRP4+, and triple seronegative gMG.

VYVGART was well-tolerated with a safety profile consistent with the established profile of VYVGART in patients with AChR-Ab seropositive gMG and other indications. No new safety concerns were identified.

ADAPT SERON Study Design
The Phase 3 ADAPT SERON study is a randomized, double-blind, placebo-controlled, multi-center study evaluating the safety and efficacy of efgartigimod in adults with AChR-Ab seronegative gMG (n=119) across North America, Europe, China, and the Middle East. Part A randomized participants (1:1) received 4 once-weekly infusions of efgartigimod IV or placebo, followed by a 5-week follow-up and primary analysis. Part B is an open-label extension: participants receive 2 fixed cycles of 4 once-weekly efgartigimod infusions (4-week interval between cycles); from cycle 3 onward, additional cycles could be started ≥1 week after the last administration of the previous cycle, based on clinical status. The primary endpoint is the MG-ADL total score change from baseline to day 29 in part A. Other scales of evaluation include QMG, MG-QoL 15r, MGC, and EQ-5D-5L VAS. Enrolled participants had a confirmed MG diagnosis by an independent panel of experts, and an MG-ADL total score of 5 or greater. Participants were on a stable dose of at least one gMG treatment prior to randomization, including acetylcholinesterase inhibitors, corticosteroids or nonsteroidal immunosuppressive drugs. Participants were eligible to enroll in ADAPT SERON if they were AChR-Ab seronegative, which included participants who are MuSK-Ab seropositive, LRP4-Ab seropositive, or triple seronegative.

MG-ADL is a validated measure of disease activity in patients living with myasthenia gravis, which evaluates the functional impact of symptoms on daily activities such as speaking, chewing, swallowing, breathing, and limb strength.

About AChR-Ab Seronegative Generalized Myasthenia Gravis (gMG)
Generalized myasthenia gravis (gMG) is a rare, chronic, neuromuscular autoimmune disease caused by pathogenic IgGs targeting the neuromuscular junction (NMJ), resulting in impaired neuromuscular transmission and debilitating and potentially life-threatening muscle weakness and chronic fatigue. Approximately 80% of patients with gMG have detectable antibodies against the AChR in sera, and these patients are diagnosed as AChR-Ab seropositive gMG. Approximately 20% of patients with gMG do not have detectable serum antibodies directed against AChR and are referred to as AChR-Ab seronegative gMG. These patients may have detectable autoantibodies targeting other NMJ proteins, such as muscle-specific tyrosine kinase (MuSK) and low-density lipoprotein receptor-related protein 4 (LRP4), or others. Anti-MuSK antibodies are detected in approximately 1-10% of patients with gMG, while anti-LRP4 antibodies are detected in approximately 1-5% of patients with gMG. About 10% of patients do not have any detectable autoantibodies against AChR, MuSK or LRP4. These triple seronegative patients have historically been excluded from studies and have a higher disease burden and unmet medical need compared to patients with detectable autoantibodies. Currently, there are no approved treatments available for patients with anti-LRP4 antibodies or for triple seronegative patients.

Important Safety 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).

IMPORTANT SAFETY INFORMATION
Do not use VYVGART if you have a serious allergy to efgartigimod alfa or any of the other ingredients in VYVGART. VYVGART can cause serious allergic reactions and a decrease in blood pressure leading to fainting.

VYVGART may cause serious side effects, including:

- **Infection.** VYVGART may increase the risk of infection. The most common infections were urinary tract and respiratory tract infections. Signs or symptoms of an infection may include 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.

- **Allergic Reactions (hypersensitivity reactions).** VYVGART can cause allergic reactions such as rashes, swelling under the skin, and shortness of breath. Serious allergic reactions, such as trouble breathing and decrease in blood pressure leading to fainting have been reported with VYVGART.
- **Infusion-Related Reactions.** VYVGART can cause infusion-related reactions. The most frequent symptoms and signs reported with VYVGART were high blood pressure, chills, shivering, and chest, abdominal, and back pain.

Tell your doctor if you have signs or symptoms of an infection, allergic reaction, or infusion-related reaction. These can happen while you are receiving your VYVGART treatment or afterward. Your doctor may need to pause or stop your treatment. Contact your doctor immediately if you have signs or symptoms of a serious allergic reaction.

Before taking VYVGART, tell your doctor if you:

- take any medicines, including prescription and non-prescription medicines, supplements, or herbal medicines,
- have received or are scheduled to receive a vaccine (immunization), or
- have any allergies or medical conditions, including if you are pregnant or planning to become pregnant, or are breastfeeding.

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 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, China and Canada 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 approved neonatal Fc receptor (FcRn) blocker and is evaluating its broad potential in multiple serious autoimmune diseases while advancing several earlier stage experimental medicines within its therapeutic franchises. For more information, visit www.argenx.com and follow us on LinkedIn, Instagram, Facebook, and YouTube.

This press release contains inside information within the meaning of Article 7(1) of the EU Market Abuse Regulation (Regulation 596/2014).

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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 “commit,” and “continue,” and include statements argenx makes concerning the potential of VYVGART to meaningfully improve the lives of seronegative gMG patients who continue to face limited treatment options; its goal to expand the use of VYVGART in a broad spectrum of patients with myasthenia gravis; its commitment to improve the lives of people suffering from severe autoimmune diseases; and its aim to translate immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. 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, including but not limited to, the results of argenx’s clinical trials; expectations regarding the inherent uncertainties associated with the development of novel drug therapies; preclinical and clinical trial and product development activities and regulatory approval requirements; the acceptance of its products and product candidates by its patients as safe, effective and cost-effective; the impact of governmental laws and regulations, including tariffs, export controls, sanctions and other regulations on its business; its reliance on third-party suppliers, service providers and manufacturers; inflation and deflation and the corresponding fluctuations in interest rates; and regional instability and conflicts. 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.