argenx Announces U.S. FDA Approval Expanding VYVGART and VYVGART Hytrulo for Use in All Adult Patients Living with gMG

- *VYVGART and VYVGART Hytrulo are the first and only approved treatments for all serotypes of adult patients living with gMG – anti-AChR-Ab positive, anti-MuSK-Ab positive, anti-LRP4-Ab positive, and triple seronegative*
- *Patients treated with VYVGART in the ADAPT SERON study experienced rapid, significant and sustained symptom improvements that continued with ongoing treatment*
- *Approval advances argenx's commitment to address the unique needs of every MG patient, delivering the broadest MG label to date*

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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 the U.S. Food and Drug Administration (FDA) approved a label expansion for VYVGART® (efgartigimod alfa-fcab) and VYVGART Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc) for the treatment of adult patients with generalized myasthenia gravis (gMG). The approved supplemental Biologics License Application (sBLA) expands VYVGART's indication to include all serotypes of adult patients living with gMG – anti-AChR-Ab positive, anti-MuSK-Ab positive, anti-LRP4-Ab positive, and triple seronegative.

The approval is based on data from the Phase 3 ADAPT SERON study, the largest study to date of patients with gMG who do not have detectable anti-acetylcholine receptor antibodies (AChR-Ab) across three serotypes – anti-MuSK-Ab positive, anti-LRP4-Ab positive, and triple seronegative. The overall population of patients in the study treated with VYVGART showed rapid, significant and sustained improvements in their gMG symptoms, including speech, vision, physical function and swallowing, among others. In addition, VYVGART was well tolerated across serotypes, with safety consistent with the established profile in patients with anti-AChR-Ab positive gMG.

"Today's approval means that all adult gMG patients, regardless of serotype, can now benefit from VYVGART's rapid onset, sustained disease control, and favorable safety profile," said Luc Truyen, M.D., Ph.D., Chief Medical Officer at argenx. "For clinicians, this simplifies treatment decisions, representing a major advancement in reaching as many patients living with gMG as possible."

"MG affects patients in various ways, and those with gMG who do not have detectable AChR antibodies need safe, effective treatments. Prior to the ADAPT SERON study, these patients were rarely included in clinical trials," 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. "MG leads to debilitating muscle weakness, causing challenges with vision, movement, speech, swallowing, and even breathing. Although many MG patients have detectable AChR-Ab, roughly 20% do not, making diagnosis and management especially difficult. The expanded indication of efgartigimod for use in all adult gMG patients enables healthcare providers to prescribe this targeted treatment more readily upon clinical diagnosis, irrespective of serotype."

Detailed results from the Phase 3 ADAPT SERON study:

- Patients showed clinically meaningful improvements in disease activity across all three serotypes – anti-MuSK-Ab positive, anti-LRP4-Ab positive, and triple seronegative.
- The primary endpoint was met (p=0.0068), demonstrating that patients treated with VYVGART achieved a statistically significant improvement in MG-ADL (Myasthenia Gravis Activities of Daily Living) total score compared to placebo at week 4.
- In the overall population – across all serotypes in the study – 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 serotypes studied.
- VYVGART was well tolerated across serotypes, with safety consistent with the established profile in patients with anti-AChR-Ab positive gMG.

"For too long, gMG patients who do not have detectable AChR-Ab have been left behind, feeling disengaged and excluded from receiving treatments that specifically treat their disease, which has led to patients experiencing a higher burden of suffering," said Allison Foss, Executive Director of the Myasthenia Gravis Association. "This approval validates that gMG patients without AChR-Ab can benefit from a targeted treatment, bringing a sense of hope to thousands in our community."

argenx recently announced positive top-line results from the ADAPT OCULUS study of VYVGART Hytrulo in ocular MG and remains focused on advancing the development of VYVGART for all patients living with MG, including pediatric gMG patient populations in the ADAPT Jr study.

VYVGART is available to patients in three administration options, including VYVGART Hytrulo self-injection with a prefilled syringe.

Access Support for VYVGART® and VYVGART Hytrulo®

The argenx patient support program, My VYVGART® Path, can help patients and healthcare providers navigate access. My VYVGART® Path resources include disease and product education, access support and benefits verification, and financial assistance programs for eligible patients. argenx is committed to supporting access for patients to its medicines.

More information is available at VYVGART.com.

About 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 positive gMG. Approximately 20% of patients with gMG do not have detectable serum antibodies directed against AChR and are referred to as having anti-AChR antibody negative 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.

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 anti-AChR antibody negative 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. Part B is an open-label period: 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 week 4 (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 anti-AChR antibody negative gMG, which included participants who are anti-MuSK-Ab positive, anti-LRP4-Ab positive, and triple seronegative.

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

See FDA-approved Important Safety Information below and full Prescribing Information for VYVGART for additional information.

Important Safety Information
What is VYVGART® (efgartigimod alfa-fcab) for intravenous (IV) infusion and what is VYVGART HYTRULO® (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection?
VYVGART and VYVGART HYTRULO are both prescription medicines used to treat adults with generalized myasthenia gravis (gMG).

It is not known if VYVGART or VYVGART HYTRULO is safe and effective in children.

IMPORTANT SAFETY INFORMATION
Do not take VYVGART if you are allergic to efgartigimod alfa or any of the ingredients in VYVGART. Do not take VYVGART HYTRULO if you are allergic to efgartigimod alfa, hyaluronidase, or any of the ingredients in VYVGART HYTRULO. VYVGART or VYVGART HYTRULO can cause serious allergic reactions and a decrease in blood pressure leading to fainting.

Before taking VYVGART or VYVGART HYTRULO, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection or fever.
- have recently received or are scheduled to receive any vaccinations.

- have any history of allergic reactions.
- have kidney (renal) problems.
- are pregnant or plan to become pregnant. It is not known whether VYVGART or VYVGART HYTRULO will harm your unborn baby.

o Pregnancy Exposure Registry. There is a pregnancy exposure registry for women who use VYVGART or VYVGART HYTRULO during pregnancy. The purpose of this registry is to collect information about your health and your baby. Your healthcare provider can enroll you in this registry. You may also enroll yourself or get more information about the registry by calling 1-855-272-6524 or going to VYVGARTPregnancy.com

- are breastfeeding or plan to breastfeed. It is not known if VYVGART or VYVGART HYTRULO passes into your breast milk.

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

VYVGART or VYVGART HYTRULO can cause side effects which can be serious, including:

- **Infection.** VYVGART or VYVGART HYTRULO may increase the risk of infection. If you have an active infection, your healthcare provider should delay your treatment with VYVGART or VYVGART HYTRULO until your infection is gone. Tell your healthcare provider right away if you get any of the following signs and symptoms of an infection: fever, chills, frequent and painful urination, cough, pain and blockage of nasal passages, wheezing, shortness of breath, sore throat, excess phlegm, and nasal discharge.

- **Allergic reactions (hypersensitivity reactions).** VYVGART or VYVGART HYTRULO can cause allergic reactions that can be severe. These reactions can happen during, shortly after, or weeks after your VYVGART infusion or VYVGART HYTRULO injection. Tell your healthcare provider or get emergency help right away if you have any of the following symptoms of an allergic reaction with VYVGART or VYVGART HYTRULO: rash, swelling of the face, lips, throat, or throat, shortness of breath, trouble breathing, low blood pressure, and fainting.

An additional symptom of an allergic reaction with VYVGART HYTRULO can include hives.

- **Infusion or injection-related reactions.** VYVGART can cause infusion-related reactions. VYVGART HYTRULO can cause infusion or injection-related reactions. These reactions can happen during or shortly after your VYVGART infusion or VYVGART HYTRULO injection. Tell your healthcare provider if you have any of the following symptoms of an infusion or injection-related reaction: high blood pressure, chills, shivering, and chest, stomach, or back pain.

The most common side effects of VYVGART or VYVGART HYTRULO include respiratory tract infection, headache, and urinary tract infection. An additional common side effect with VYVGART HYTRULO includes injection site reactions.

These are not all the possible side effects of VYVGART or VYVGART HYTRULO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see the full **Prescribing Information** for VYVGART and full **Prescribing Information** for VYVGART HYTRULO.

About VYVGART and VYVGART Hytrulo

VYVGART® (efgartigimod alfa fcab) is a first-in-class human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG autoantibodies. VYVGART Hytrulo® is a subcutaneous combination of efgartigimod alfa (VYVGART) and recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology to facilitate subcutaneous injection delivery of biologics. VYVGART is approved for generalized myasthenia gravis (gMG) and immune thrombocytopenia (Japan only). VYVGART Hytrulo is approved for gMG and chronic inflammatory demyelinating polyneuropathy (CIDP). VYVGART Hytrulo may be marketed under different proprietary names in other regions.

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 "advance," "aim," "bring," "can," "commit," "continue," and "expand," and include statements argenx makes concerning the Approval's advancing of argenx's commitment to address the unique needs of every MG patient, delivering the broadest MG label to date; its belief that all adult gMG patients, regardless of serotype, can now benefit from VYVGART's rapid onset, sustained disease control, and favorable safety profile; its belief that the Approval represents a major advancement in reaching as many patients living with gMG as possible; its commitment to advancing the development of VYVGART for all patients living with MG, including pediatric gMG patient populations in the ADAPT Jr study; its commitment to improve the lives of people suffering from severe autoimmune diseases; its aim to translate immunology breakthroughs into a world-class portfolio of novel antibody-based medicines; its commercialization of the first approved neonatal Fc receptor (FcRn) blocker; the FcRn blocker's broad potential in multiple serious autoimmune diseases; and its advancement of several earlier-stage experimental medicines within its therapeutic franchises. 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.