argenx Announces European Commission Approval of VYVGART Subcutaneous Injection for Chronic Inflammatory Demyelinating Polyneuropathy

- *VYVGART® SC, first-and-only IgG Fc-antibody fragment which specifically targets the neonatal Fc receptor (FcRn), now approved for use in Europe for CIDP*
- *Approval based on ADHERE clinical trial, the largest study of CIDP patients to date*
- *First novel mechanism of action for CIDP treatment in more than 30 years*

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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 European Commission (EC) approved VYVGART® (efgartigimod alfa) 1000mg for subcutaneous (SC) injection as a monotherapy for the treatment of adult patients with progressive or relapsing active chronic inflammatory demyelinating polyneuropathy (CIDP) after prior treatment with corticosteroids or immunoglobulins. VYVGART for SC injection is available as a vial or prefilled syringe and can be administered by a patient, caregiver, or healthcare professional. Treatment is initiated with a weekly dose regimen and may be adjusted to every other week based on clinical evaluation.

"The EC's decision has been met with hope and enthusiasm by the European Patient Organisation for Dysimmune and Inflammatory Neuropathies (EPODIN). We see the introduction of a new targeted therapy for CIDP as a major step forward for the patient community," said Jean-Philippe Plançon, President of EPODIN.

CIDP is a rare, debilitating, often progressive, immune-mediated neuromuscular disorder of the peripheral nervous system. Patients experience a range of disabling mobility and sensory issues, including trouble standing from a seated position, pain and fatigue, and frequent tripping or falling. People living with CIDP can also become wheelchair bound and unable to work as the disease progresses. Currently, 85% of patients require ongoing treatment and nearly 88% of treated patients experience residual impairment and disability.

“CIDP can severely affect quality of life by causing weakness, loss of balance and mobility, numbness and pain in a patient’s arms and legs. For far too long, physicians have had limited options for helping to improve patient outcomes,” said Dr. Luis Querol, M.D., Ph.D., ADHERE Investigator, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain. “The approval of VYVGART SC for the treatment of CIDP marks a turning point in clinical practice, as physicians now have access to a new, effective treatment option that, for the first time, precisely targets a key mechanism of disease and provides meaningful functional improvements to patients.”

The EC approval follows a positive recommendation from the Committee for Medicinal Products for Human Use (CHMP) and is based on positive results from the ADHERE clinical trial, the largest study of CIDP patients to date. In the study, 66.5% (214/322) of patients treated with VYVGART SC demonstrated evidence of clinical improvement, including in mobility, function and strength. Clinical benefit was seen across all patient subtypes, regardless of prior treatment. ADHERE met its primary endpoint ($p<0.0001$) demonstrating a 61% reduction (HR: 0.39 95% CI: 0.25; 0.61) in the risk of relapse versus placebo. 99% of trial participants elected to participate in the ADHERE open-label extension. The safety results were consistent with the known safety profile of VYVGART SC in previous clinical studies.

“VYVGART SC is the first therapy with a novel mechanism of action to be approved for this community in more than 30 years,” said Luc Truyen, M.D., Ph.D., Chief Medical Officer of argenx. “With VYVGART SC, CIDP patients and physicians across Europe will soon have access to an effective novel therapy with a favorable safety profile that has a precise mechanism of action and a convenient self-injection option. This approval further affirms the potential of efgartigimod in IgG-mediated autoimmune diseases.”

The EC approval will apply to all 27 European Union Member States, and also to Iceland, Liechtenstein, and Norway. argenx is working closely with local regulatory authorities across the region to ensure that patients who may benefit from VYVGART SC are able to access the novel treatment as soon as possible.

This regulatory approval is the second for VYVGART SC in Europe, which first received approval as an add-on to standard therapy for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.

About ADHERE
The ADHERE trial was a multi-center, randomised, double-blind, placebo-controlled trial evaluating efgartigimod alfa SC for the treatment of CIDP. ADHERE enrolled 322 adult patients with CIDP, 130 of whom were based in Europe. The trial consisted of an open-label Stage A followed by a randomized, placebo-controlled Stage B. In order to be eligible for the trial, the diagnosis of CIDP was confirmed by an independent panel of experts. Patients entered a run-in stage, where any ongoing CIDP treatment was stopped and, in order to be eligible for Stage A, had to demonstrate active disease with clinically meaningful worsening on at least one CIDP clinical assessment tool, including INCAT, I-RODS, or mean grip strength. Treatment-naïve patients were able to skip the run-in period with proof of recent worsening. To advance to Stage B, patients needed to demonstrate evidence of clinical improvement (ECI) with efgartigimod alfa SC. ECI was achieved through improvement of the INCAT score, or improvement on I- RODS or mean grip strength if those scales had demonstrated worsening during the run-in period. In Stage B, patients were randomized to either efgartigimod alfa SC or placebo for up to 48 weeks. The primary endpoint was measured once 88 total relapses or events were achieved in Stage B and was based on the hazard ratio for the time to first adjusted INCAT deterioration (i.e. relapse). After Stage B, all patients had the option to roll-over to an open-label extension study to receive efgartigimod alfa SC.

About Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
CIDP is a rare and serious autoimmune disease of the peripheral nervous system. There is increasing evidence that IgG antibodies play a key role in the damage to the peripheral nerves. People with CIDP experience fatigue, muscle weakness and a loss of feeling in their arms and legs that can worsen over time or may come and go. These symptoms can significantly impair a person's ability to function in their

daily lives. Without treatment, one-third of people living with CIDP will need a wheelchair.

About Efgartigimod SC
Efgartigimod SC (efgartigimod alfa) is a human IgG1 antibody fragment designed to reduce pathogenic immunoglobulin G (IgG) antibodies by binding to the neonatal Fc receptor (FcRn) and blocking the IgG recycling process. Efgartigimod SC is the first-approved FcRn blocker globally and is marketed as VYVGART® Hytrulo in the United States and China for the treatment of generalized myasthenia gravis (gMG) and CIDP; as VYVDURA in Japan for gMG and CIDP; and as VYVGART for gMG and CIDP in other regions globally. Efgartigimod SC is currently being evaluated in more than 15 severe autoimmune diseases where pathogenic IgGs are believed to be mediators of disease.

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 commercialising 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.

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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 “aim,” “is,” “can,” “may,” “will,” and “believe” and include statements argenx makes concerning argenx’s aim to translate immunology breakthroughs into a world-class portfolio of novel antibody-based medicines; its belief that the approval of VYVGART SC for the treatment of CIDP may bring meaningful functional improvements to patients; the timing of access to an effective novel therapy for CIDP patients and physicians across Europe; and the potential of efgartigimod in IgG-mediated autoimmune diseases. 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.