**argenx Announces Positive CHMP Opinion for VYVGART (efgartigimod alfa) Subcutaneous Injection for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)**

- *VYVGART® is first-and-only targeted IgG Fc-antibody fragment for CIDP*
- *First novel mechanism of action for CIDP treatment in more than 30 years*
- *CHMP positive opinion based on ADHERE data, the largest ever CIDP clinical trial*
- *European Commission (EC) decision on marketing authorization application (MAA) expected within approximately two months*

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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 Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended European Commission (EC) approval of VYVGART® 1000mg (efgartigimod alfa) 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.

“Our mission is to develop innovative, targeted treatments for patients with rare and severe autoimmune diseases, who continue to face significant unmet needs. The positive CHMP opinion for VYVGART in CIDP brings us one step closer to providing patients across Europe with a transformational new treatment option that provides meaningful functional improvement,” said Luc Truyen M.D., Ph.D., Chief Medical Officer, argenx. “VYVGART is the first and only targeted IgG Fc-antibody fragment for CIDP and if approved, would mark the first treatment in Europe with a novel, precision mechanism of action for CIDP patients in 30 years.”

VYVGART for subcutaneous 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 CHMP recommendation is based on positive results from the ADHERE clinical trial, the largest study of CIDP patients to date. In the ADHERE study, 66.5% (214/322) of patients treated with VYVGART, regardless of prior treatment, demonstrated evidence of clinical improvement, including improvements in mobility, function and strength. 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. The study also demonstrated functional improvements across the Inflammatory Neuropathy Cause and Treatment (INCAT) disability scores (>1-point), grip strength (>17 kPa) and I-RODS scale (>8 points) at week 36 compared to baseline at entry to standard of care withdrawal phase. Ninety-nine percent of trial participants elected to participate in the ADHERE open-label extension. The safety results were generally consistent with the known safety profile of VYVGART in previous clinical studies.

"For the patient population represented by the European Patient Organisation for Dysimmune and Inflammatory Neuropathies (EPODIN) and for those affected by CIDP, this is excellent news," said Jean-Philippe Plançon, President of EPODIN. "There are still considerable unmet medical needs in the management of CIDP, and the CHMP’s recommendation brings renewed hope for improved treatment options and quality of life."

The positive CHMP opinion is a scientific recommendation for marketing authorization, serving as a basis for the EC's final decision on argenx's CIDP application for subcutaneous VYVGART. The EC is expected to make a decision following CHMP recommendation and the decision will apply to all 27 European Union Member States, and also to Iceland, Norway and Liechtenstein. Currently, VYVGART is indicated 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 multicenter, randomized, double-blind, placebo-controlled trial evaluating SC efgartigimod alfa for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP). ADHERE enrolled 322 adult patients with CIDP, 130 of whom were based in Europe, who were off treatment (not on active treatment within the past six months or newly diagnosed) or being treated with immunoglobulin therapy or corticosteroids. 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 SC efgartigimod alfa. 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 SC efgartigimod alfa 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 SC efgartigimod alfa.

**About Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)**

Chronic inflammatory demyelinating polyneuropathy (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. There are an estimated 31,413 people living with CIDP in the European Union.

**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 IV and SC formulation. SC efgartigimod is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology. In August 2022, efgartigimod received approval from the EC for IV administration as an add on to standard therapy for the treatment of adult patients with gMG who are AChR antibody positive.

**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.

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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," "are," "believe," "can," "continue," "expect," "may," and "will" and include statements argenx makes concerning the expected timing and decision of the EC regarding VYVGART for SC injection for CIDP treatment and the application of such decision; the potential for improved treatment options and quality of life; and its goal of translating 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.