argenx Announces Positive CHMP Opinion for Subcutaneous Efgartigimod for Generalized Myasthenia Gravis

- *Positive opinion based on Phase 3 ADAPT-SC study demonstrating noninferior total IgG reduction at day 29 with subcutaneously (SC) administered efgartigimod, compared to intravenous (IV) administration*

- *European Commission (EC) decision on marketing authorization application (MAA) expected within approximately 60 days*

Amsterdam, The Netherlands—September 15, 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 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended EC approval of the SC injectable formulation of efgartigimod 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. SC efgartigimod is formulated with Halozyme's ENHANZE® drug delivery technology to facilitate subcutaneous delivery of biologics.

"Generalized myasthenia gravis is a complex and devastating disease that is debilitating for people who live with it, making routine movements exhausting and challenging to perform," said Prof. dr. Jan De Bleecker, Ghent University Hospital and Ghent University. "I'm pleased to learn of the CHMP's positive opinion as it represents a significant advancement for the gMG community who would benefit from an additional, effective treatment option that can improve quality of life and better manage this chronic condition. In particular, SC efgartigimod has the potential to have a positive impact on treatment convenience, leading to a broader positive impact for patients and healthcare systems."

"The positive recommendation by the CHMP for the SC injectable formulation of efgartigimod brings us one step closer to broadening our treatment offering for people living with gMG in Europe," said Anant Murthy, Ph.D., General Manager, EMEA, argenx. "Our mission is to transform the treatment of severe autoimmune disease, and we remain committed to providing gMG patients a second innovation that could further address treatment burden. We are particularly pleased with the possibility for self-administration of the SC formulation, which may provide additional treatment flexibility for physicians and patients."

The CHMP recommendation is based on positive results from the Phase 3 ADAPT-SC study. The ADAPT-SC trial met its primary endpoint of noninferiority, where SC efgartigimod demonstrated a mean total IgG reduction of 66.4% from baseline at day 29, compared to 62.2% with the IV formulation. Additional key secondary endpoints were met, which were consistent with efficacy measures from the ADAPT IV study identifying the correlation between IgG reduction and clinical benefit in gMG.

SC efgartigimod has a demonstrated safety profile, consistent with the ADAPT IV clinical trial with the exception of injection site reactions (ISRs), which are commonly observed with biologics administered subcutaneously. ISRs were mild to moderate and did not lead to treatment discontinuation.

The positive CHMP opinion is a scientific recommendation for marketing authorization, serving as a basis for the EC's final decision on argenx's application for SC efgartigimod. The EC is expected to make a decision within approximately 60 days following CHMP recommendation. The decision will apply to all 27 European Union Member States, and also to Iceland, Norway and Liechtenstein.

About Phase 3 ADAPT-SC Trial

The Phase 3 ADAPT-SC trial was a multicenter, randomized, open-label, parallel-group study evaluating the noninferiority of the pharmacodynamic (PD) effect of SC efgartigimod compared with IV efgartigimod in adult patients with gMG. The PD effect was measured by percent change from baseline in autoantibody (AChR) levels at day 29. Safety, clinical efficacy, immunogenicity and pharmacokinetics (PK) were also assessed. A total of 110 adult patients with gMG in North America, Europe and Japan enrolled in the ADAPT-SC trial. Patients were randomized in a 1:1 ratio to receive SC efgartigimod for one treatment cycle consisting of four doses at once-weekly intervals. The total study duration was approximately 12 weeks, including seven weeks of follow-up after the treatment cycle. At the completion of ADAPT-SC, patients had the opportunity to roll-over to ADAPT-SC+, an open-label extension study.

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 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 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., Japan, Israel, the EU and the UK. The Company is evaluating efgartigimod in multiple serious autoimmune diseases and advancing several earlier stage experimental medicines within its therapeutic franchises.

For further information, please contact:

Media:

Erin Murphy
EMurphy@argenx.com

Investors:

Alexandra Roy (US)
ARoy@argenx.com

Lynn Elton (EU)
LElton@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 the timing of approval or marketing authorization by the EC of the SC injectable formulation of efgartigimod as an add on to standard therapy for the treatment of adult patients with gMG who are AChR antibody positive; and the benefits and impact of SC efgartigimod on patients, physicians and healthcare systems. 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.

# # #