argenx Announces European Commission Approval of Subcutaneous VYVGART® (efgartigimod alfa) for Generalized Myasthenia Gravis

VYVGART® is now approved for both intravenous (IV) and self-administered subcutaneous (SC) use in Europe

argenx is committed to continued collaboration with local authorities across the region to enable broad access to VYVGART SC for eligible patients

Amsterdam, The Netherlands—[November 16, 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 European Commission (EC) approved SC injectable VYVGART (efgartigimod alfa) as an add-on to standard therapy for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. The EC previously approved VYVGART IV in August 2022. Following this decision, VYVGART is now approved in Europe for both IV and self-administered SC use. The approval is applicable to all 27 European Union (EU) Member States plus Iceland, Norway and Liechtenstein. argenx will work with local health authorities to secure patient access for VYVGART SC in the region.

"Today's approval reflects our commitment to providing a choice of effective, innovative therapies to people with autoimmune disease. We are proud to deliver this second formulation to the European gMG community, just 15 months after the initial approval of VYVGART IV," said Anant Murthy, General Manager of argenx EMEA. "The availability of two formulations, including the possibility for patients to self-administer at home, allows people living with gMG to choose the treatment that best works for their lifestyle, further reinforcing the individualized treatment approach offered by VYVGART."

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 Phase 3 ADAPT-SC study. ADAPT-SC established the efficacy of VYVGART SC by demonstrating a reduction in anti-AChR antibody levels comparable to VYVGART IV in adult gMG patients. ADAPT-SC was a bridging study to the Phase 3 ADAPT study, which formed the basis for approval of VYVGART IV in Europe in August 2022.

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 VYVGART SC compared with

VYVGART IV in adult patients with gMG. The pharmacodynamic effect was measured by percent change from baseline for both total IgG and AChR autoantibody 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 VYVGART IV or SC 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 VYVGART® SC

VYVGART SC is a SC injectable formulation of efgartigimod alfa, a human IgG1 antibody fragment marketed for intravenous use as VYVGART. It is formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology, to facilitate SC injection delivery of biologics. In binding to the neonatal Fc receptor (FcRn), VYVGART results in the reduction of circulating IgG autoantibodies. VYVGART SC was approved in the United States in June 2023 and is marketed as VYVGART® Hytrulo.

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 approved neonatal Fc receptor (FcRn) blocker in the U.S., Japan, Israel, the EU, the UK, Canada and China. The Company is evaluating efgartigimod in multiple serious autoimmune diseases and advancing several earlier stage experimental medicines within its therapeutic franchises.

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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 "aims," "believes," "hope," "estimates," "anticipates," "expects," "intends," "may," "will," "should," or "commitment" and include statements argenx makes concerning the approval by the European Commission (EC) of SC injectable VYVGART™ (efgartigimod alfa) 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 and argenx's commitment to collaborating with local authorities across the European Union to enable broad access to VYVGART for eligible patients for both IV and self-administered SC use. 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 argenx's expectations regarding the inherent uncertainties associated with development of novel drug therapies, preclinical and clinical trial and product development activities and regulatory approval requirements; the acceptance of our products and product candidates by our patients as safe, effective and cost-effective, and the impact of governmental laws and regulations on our business. 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 publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.