**argenx Receives Notification of PDUFA Date Extension for SC Efgartigimod**

**January 27, 2023**

**Amsterdam, the Netherlands —** argenx (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced that the U.S. Food and Drug Administration (FDA) has extended the review of the Biologics License Application (BLA) for subcutaneous (SC) efgartigimod (1000mg efgartigimod-PH20) for the treatment of adult patients with generalized myasthenia gravis (gMG) to June 20, 2023.

The FDA notified argenx on January 26, 2023 that information submitted in connection with the ongoing review of the SC efgartigimod BLA constituted a major amendment and requires an extension to allow sufficient time to review. No additional data or studies have been requested at this time.

“We are confident in the profile of SC efgartigimod and the strength of the ADAPT-SC dataset showing noninferiority of our subcutaneous product to VYVGART®. We will continue to work closely with the FDA as it completes its review to bring this important medicine to people living with gMG," said Luc Truyen, M.D., Ph.D., Chief Medical Officer, argenx.

**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 intravenous and subcutaneous (SC) formulation. SC efgartigimod is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology.

**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., the EU and Japan.

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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 "believes," "hope," "estimates," "anticipates," "expects," "intends," "may," "will," or "should" and include statements argenx makes concerning the profile of subcutaneous (SC) efgartigimod and the strength of the ADAPT-SC dataset; the initiation, timing, progress and results of its anticipated clinical development and regulatory milestones and plans; and the timing and outcome of regulatory filings and regulatory approvals. 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 publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.*