argenx Announces VYVGART (efgartigimod alfa) Authorized for Sale by Health Canada for Generalized Myasthenia Gravis

- *VYVGART® is the first-and-only neonatal Fc receptor (FcRn) blocker authorized for sale in Canada*
- *Approval based on the positive Phase 3 ADAPT trial (p<0.0001) showing 68% of VYVGART-treated patients were responders on the MG-ADL scale compared to 30% of placebo patients after one treatment cycle*

Amsterdam, The Netherlands —Sep. 21, 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 Health Canada has issued a Notice of Compliance authorizing VYVGART® (efgartigimod alfa) for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. With this regulatory milestone, VYVGART is the first-and-only neonatal Fc receptor (FcRn) blocker authorized for sale in Canada.

“There continues to be a significant unmet medical need for people living with gMG, who face debilitating muscle weakness and mobility issues. We are very excited by the authorization of VYVGART for sale in Canada, bringing a safe and effective treatment option to patients and clinicians that targets the underlying driver of gMG by reducing IgG autoantibodies,” said Dr. Vera Bril, Professor of Medicine (Neurology) at the University of Toronto, Director of the Neuromuscular Section, Division of Neurology, University of Toronto and University Health Network.

“Living with gMG can significantly impact a person’s independence and affect basic personal tasks, such as speaking, chewing and swallowing food, and brushing teeth and hair, and in some severe cases, it can also affect breathing. The gMG community in Canada has long awaited new effective treatment advancements for this rare condition. Today’s announcement brings new hope for people with gMG, and we look forward to seeing the important impact of this additional treatment option,” said Stacey Lintern, Chief Executive Officer, Muscular Dystrophy Canada.

The authorization of VYVGART is based on results from the global Phase 3 ADAPT trial, which were published in the July 2021 issue of *The Lancet Neurology*. The ADAPT trial met its primary endpoint, demonstrating that significantly more anti-AChR antibody positive gMG patients were responders on the MG-ADL scale following treatment with VYVGART compared with placebo (68% vs. 30%; p<0.0001) and on the Quantitative Myasthenia Gravis (QMG) scale (63% VYVGART vs. 14% placebo; p<0.0001).

VYVGART had a demonstrated safety profile in the ADAPT clinical trial. The most common adverse events in ADAPT were headache (29% vs 28% placebo), upper respiratory tract infection (11% vs 5% placebo), and urinary tract infection (10% vs. 5% placebo).

“Today is an important day for us as we deliver on our commitment to the gMG community to make VYVGART available to patients in Canada,” said John Haslam, General Manager argenx Canada. “For the first time, people living with gMG in Canada will have a treatment option that is targeted to the biology of their disease, which is both well-tolerated and effective in managing symptoms.”

About VYVGART

VYVGART is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG autoantibodies. It is the first approved FcRn blocker in the United States, EU and China for the treatment of adults with generalized myasthenia gravis (gMG) who are anti- acetylcholine receptor (AChR) antibody positive and in Japan for the treatment of adults with gMG who do not have sufficient response to steroids or non-steroidal immunosuppressive therapies (ISTs).

About Phase 3 ADAPT Trial

The Phase 3 ADAPT trial was a 26-week randomized, double-blind, placebo-controlled, multi-center, global trial evaluating the safety and efficacy of VYVGART in adult patients with gMG. A total of 167 adult patients with gMG in North America, Europe and Japan enrolled in the trial. Patients were randomized in a 1:1 ratio to receive VYVGART or placebo, in addition to stable doses of their current gMG treatment. ADAPT was designed to enable an individualized treatment approach with an initial treatment cycle followed by subsequent treatment cycles based on clinical evaluation. The primary endpoint was the comparison of percentage of MG-ADL responders in the first treatment cycle between VYVGART and placebo treatment groups in the anti-AChR antibody positive population. Responders were defined as having at least a two-point reduction on the MG-ADL scale sustained for four or more consecutive weeks during the first treatment cycle.

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,[1] where muscles throughout the body may be affected. Patients with confirmed AChR antibodies account for approximately 85% of the total gMG population.[1]

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 and China. The Company is evaluating efgartigimod in multiple serious autoimmune diseases and advancing several earlier stage experimental medicines within its therapeutic franchises. For

more information, visit www.argenx.com and follow us on LinkedIn, Twitter, and Instagram.

References

[1] Behin et al. New Pathways and Therapeutics Targets in Autoimmune Myasthenia Gravis. J Neuromusc Dis 5. 2018. 265-277

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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 availability of VYVGART® for sale in Canada; the potential impact of VYVGART® on people living with gMG in Canada; and the benefits and safety profile of VYVGART®. 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.

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