argenx Announces European Commission Approval of VYVGART™ (efgartigimod alfa-fcab) for the Treatment of Generalized Myasthenia Gravis News August 11, 2022

August 12, 2022

- VYVGART is the first neonatal Fc receptor (FcRn) blocker approved in Europe for the treatment of adults living with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive
- 68% of anti-AChR antibody positive gMG patients treated with VYVGART were responders (n=44/65) on the Myasthenia Gravis Activities of Daily Living (MG-ADL) scale compared with 30% of patients treated with placebo (n=19/64) (p<0.0001) during the first treatment cycle in the Phase 3 ADAPT trial
- argenx is committed to collaborating with local authorities across the European Union to enable broad access to VYVGART for eligible patients

argenx (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) has granted marketing authorization for VYVGART™ (efgartigimod alfa-fcab) 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.

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 market access for VYVGART across the EU.

“Now, for the first time, people living with gMG in the EU will have a treatment option that is targeted to the biology of their disease, well-tolerated, and effective in managing symptoms. We are proud to bring the first-and-only approved FcRn blocker to the EU on the heels of our U.S. and Japan launches, and remain steadfast in our mission to make VYVGART available to patients across the globe," said Tim Van Hauwermeiren, Chief Executive Officer of argenx. “We are also committed to supporting broad access to our innovative therapy, and look forward to collaborating with local health authorities to secure sustainable access agreements so we can help alleviate the burden of this debilitating disease for as many eligible patients as possible across the EU.”

The EC approval 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 Myasthenia Gravis Activities of Daily Living (MG-ADL) scale following treatment with efgartigimod compared with placebo (68% vs. 30%; p<0.0001). 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.

There were also significantly more responders on the Quantitative Myasthenia Gravis (QMG) scale following treatment with efgartigimod compared with placebo (63% vs. 14%; p<0.0001). Responders were defined as having at least a three-point reduction on the QMG scale sustained for four or more consecutive weeks during the first treatment cycle.

VYVGART had a demonstrated safety profile in the ADAPT clinical trial. The most commonly reported adverse reactions were upper respiratory tract infections (10.7% following treatment with efgartigimod vs. 4.8% of placebo) and urinary tract infections (9.5% vs. 4.8%).

“People living with gMG in the EU have long faced a significant unmet medical need due to limitations of commonly used therapies. The EC approval of VYVGART adds an important new tool for clinicians providing care to these patients with a demonstrated efficacy and safety profile observed in clinical trials,” said Renato Mantegazza, M.D., Professor at the Department of Neuroimmunology and Neuromuscular Diseases, Fondazione IRCCS Istituto Neurologico Carlo Besta, Milan, Italy, and ADAPT trial investigator. “Living with gMG can severely impair a person’s ability to complete basic personal tasks. Now, patients and families living with the devastating impact of this disease have an effective treatment option that may help to significantly improve their quality of life.”

VYVGART is the first-and-only approved FcRn blocker in the U.S. and the EU for the treatment of adult gMG patients who are anti-AChR antibody positive, and in Japan for patients who do not have sufficient response to steroids or non-steroidal immunosuppressive therapies (ISTs). argenx’s plans remain on track to launch VYVGART in Canada, China through its collaboration with Zai Lab, and select additional regions.

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 efgartigimod 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 efgartigimod 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 efgartigimod and placebo treatment groups in the anti-AChR antibody positive population.

About VYVGART

VYVGART (efgartigimod alfa-fcab) is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating immunoglobulin G (IgG) autoantibodies. It is the first and only approved FcRn blocker. VYVGART is approved in the United States and Europe 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 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].

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

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.

For further information, please contact:

Media:

Kelsey Kirk
kkirk@argenx.com

Investors:

Beth DelGiacco
bdelgiacco@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 approval by the EC of VYVGART™ (efgartigimod alfa-fcab) 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 ability to collaborate with local authorities across the European Union to enable broad access to VYVGART for eligible patients, as well as argenx's plans for launch in other regions. 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.