argenx Announces the UK MHRA has Granted Early Access to Efgartigimod for Generalized Myasthenia Gravis

Positive scientific opinion under Early Access to Medicines Scheme (EAMS) will make efgartigimod available to eligible generalized myasthenia gravis (gMG) patients in the UK prior to marketing authorization

Efgartigimod was granted a Promising Innovative Medicine (PIM) designation by UK's Medicines and Healthcare products Regulatory Agency (MHRA) in November 2021

Breda, the Netherlands—May 31, 2022—argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced that efgartigimod, the Company's neonatal Fc receptor (FcRn) blocker has been awarded a positive scientific opinion by the MHRA under the EAMS. Within the EAMS, efgartigimod is indicated for the treatment of adult patients with anti-acetylcholine receptor (AChR) antibody seropositive gMG, including patients with refractory gMG who have failed, not tolerated or are ineligible for licensed treatment.

The EAMS program offers early access to innovative medicines for patients who are experiencing a significant unmet medical need, before the MHRA approves a formal marketing authorization application (MAA) and prior to reimbursement. The positive scientific opinion enables healthcare providers to decide whether to prescribe a treatment before licensing is approved, granting eligible gMG patients in the UK the potential for early, pre-license access to efgartigimod while relevant regulatory bodies complete the review of the MAA.

"Despite currently available treatments, gMG patients in the UK face a significant disease burden and many struggle to manage the debilitating symptoms of this rare autoimmune disease. We are committed to addressing this unmet need, and are thrilled that UK healthcare professionals now have a potential new option for the treatment of their eligible gMG patients," said David Knechtel, UK Country Manager at argenx. "The MHRA's positive scientific opinion supports our belief in the value efgartigimod can offer to people living with gMG, and marks another advancement toward our goal of serving patients around the world. We look forward to continued collaboration with the agency to make this innovative therapy available to UK patients as soon as possible."

The European Medicines Agency (EMA) is currently reviewing the MAA for efgartigimod for the treatment of gMG, with a decision expected in the second half of 2022, followed by an anticipated decision from the MHRA on a UK marketing authorization. Efgartigimod was previously granted a PIM designation by the MHRA in November 2021.

About Generalized Myasthenia Gravis
Generalized myasthenia gravis (gMG) is a rare and chronic autoimmune disease, impacting up to 15,000 UK patients, where immunoglobulin G (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 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. It is currently approved in the United States for the treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive, and Japan for adult patients with gMG who do not have sufficient response to steroids or non-steroidal immunosuppressive therapies.

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. and Japan.

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 future availability of efgartigimod for the treatment of adult patients with AChR-antibody seropositive gMG and the timing of any approval or marketing authorization by the EMA and the UK of the use of efgartigimod for the treatment of gMG. 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.###