argenx Announces FDA Acceptance of BLA Filing for Efgartigimod for the Treatment of Generalized Myasthenia Gravis

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Regulated Information/Inside Information

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- If approved, efgartigimod will be the first-and-only approval of an FcRn antagonist
- Prescription Drug User Fee Act (PDUFA) target action date is December 17, 2021
- Pre-approval access program opened in U.S. for efgartigimod for eligible people living with gMG

Breda, the Netherlands – March 2, 2021 – argenx (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancers, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Biologics License Application (BLA) for intravenous (IV) efgartigimod, the company's investigational FcRn antagonist and lead product candidate, for the treatment of generalized myasthenia gravis (gMG). The FDA has set a standard 10-month review process with a PDUFA target action date of December 17, 2021.

"This is an important milestone for argenx in our transition to a commercial-stage company and brings us closer to our mission to reach patients living with gMG, a debilitating neuromuscular disease," said Tim Van Hauwermeiren, Chief Executive Officer of argenx. "We look forward to closely collaborating with the FDA through the BLA review process and to potentially making our first medicine available."

The BLA included results from the pivotal Phase 3 ADAPT trial evaluating the safety and efficacy of efgartigimod for the treatment of patients with gMG. ADAPT met its primary endpoint defined as percentage of responders on the Myasthenia Gravis Activities of Daily Living (MG-ADL) score among acetylcholine receptor-antibody positive (AChR-Ab+) gMG patients. 67.7% of AChR-Ab+ patients treated with efgartigimod achieved the primary endpoint compared with 29.7% on placebo ($p<0.0001$). Further, 40% of patients treated with efgartigimod achieved minimal symptom expression defined as MG-ADL scores of 0 (symptom free) or 1, compared to 11.1% of those who received placebo. The safety profile of efgartigimod was comparable to placebo. After completing ADAPT, 90% of participants entered ADAPT+, a three-year open-label extension study evaluating the long-term safety and tolerability of efgartigimod. There are currently 118 patients still enrolled in ADAPT+.

argenx also announced today the opening of its pre-approval access (PAA) program in the U.S., which will allow eligible people living with gMG to receive treatment with efgartigimod. The purpose of the PAA is to open availability of an investigational treatment to people who have a high degree of unmet clinical need with gMG and are not able to participate in a clinical trial.

argenx is also on track to submit an application for efgartigimod to Japan's Pharmaceuticals and Medical Devices Agency (PMDA) in the first half of 2021 and the European Medicines Agency (EMA) in the second half of 2021.

About Efgartigimod

Efgartigimod is an investigational antibody fragment designed to reduce disease-causing immunoglobulin G (IgG) antibodies and block the IgG recycling process. Efgartigimod binds to the neonatal Fc receptor (FcRn), which is widely expressed throughout the body and plays a central role in rescuing IgG antibodies from degradation. Blocking FcRn reduces IgG antibody levels representing a logical potential therapeutic approach for several autoimmune diseases known to be driven by disease-causing IgG antibodies, including: myasthenia gravis (MG), a chronic disease that causes muscle weakness; pemphigus vulgaris (PV), a chronic disease characterized by severe blistering of the skin; immune thrombocytopenia (ITP), a chronic bruising and bleeding disease; and chronic inflammatory demyelinating polyneuropathy (CIDP), a neurological disease leading to impaired motor function.

About Myasthenia Gravis

Myasthenia gravis (MG) is a rare and chronic autoimmune disease, often causing debilitating and potentially life-threatening muscle weakness. More than 85% of people with MG progress to generalized MG (gMG) within 18 months, where muscles throughout the body may be affected, resulting in extreme fatigue and difficulties with facial expression, speech, swallowing and mobility. In more life-threatening cases, MG can affect the muscles responsible for breathing. There are approximately 65,000 people in the United States and 20,000 people in Japan living with the disease

About argenx

argenx is a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer. 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 is evaluating efgartigimod in multiple serious autoimmune diseases, and

cusatuzumab in hematological cancers in collaboration with Janssen. argenx is also advancing several earlier stage experimental medicines within its therapeutic franchises. argenx has offices in Belgium, the United States, and Japan. For more information, visit www.argenx.com and follow us on LinkedIn at https://www.linkedin.com/company/argenx/ and Twitter at https://twitter.com/argenxglobal.

Media:
Kelsey Kirk
kkirk@argenx.com

Investors:
Beth DelGiacco
bdelgiacco@argenx.com

Joke Comijn (EU)
jcomijn@argenx.com

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, estimates, anticipates, expects, intends, may, will, or should, and include statements argenx makes concerning; its clinical development and regulatory plans, including the timing and outcome of regulatory filings and approvals, including those with FDA, PMDA and EMA described in this announcement and the timing and progress of commercialization activities. 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 the effects of the COVID-19 pandemic, the inherent uncertainties associated with preclinical and clinical trial and product development activities and regulatory approval requirements; argenx's reliance on collaborations with third parties; estimating the commercial potential of argenx's product candidates; argenx's ability to obtain and maintain protection of intellectual property for its technologies and drugs; argenx's limited operating history; and argenx's ability to obtain additional funding for operations and to complete the development and commercialization of its product candidates. 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.

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