argenx Announces Validation of European Marketing Authorization Application for Efgartigimod in Generalized Myasthenia Gravis

- Validation initiates formal evaluation of application which started on August 19, 2021; decision expected mid-2022
- If approved, efgartigimod will be the first-and-only approved FcRn antagonist in Europe
- Regulatory reviews of efgartigimod for generalized myasthenia gravis currently underway in the U.S., Japan and Europe

Breda, the Netherlands – August 25, 2021 – argenx (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer, today announced that it has submitted, and the European Medicines Agency (EMA) has validated, the marketing authorization application (MAA) for the Company's investigational FcRn antagonist, efgartigimod, for the treatment of generalized myasthenia gravis (gMG). Validation of the MAA confirms that the application is sufficiently complete to begin the formal review process.

The MAA is supported by results from the pivotal Phase 3 ADAPT trial evaluating the safety and efficacy of efgartigimod for the treatment of patients with gMG.

"gMG is a severe, chronic and debilitating disease that can be unpredictable and greatly impact a person's quality of life. The EMA's validation is an exciting step closer to our goal of helping people globally who are living with this disease in which there remains a significant unmet need." said Tim Van Hauwermeiren, Chief Executive Officer of argenx. "We have been building an experienced commercial team in Europe and look forward to our continued collaboration with European regulatory authorities through the review process."

"There remains a significant unmet need for new gMG treatment options that are targeted to the underlying pathogenesis of the disease and supported by clinical data," commented Prof. Dr. Andreas Meisel, Senior Physician of Neurology, Head of Myasthenia Gravis Outpatient Clinic at the Department of Neurology, Charité – Universitätsmedizin Berlin, and Principal Investigator on the ADAPT study. "Myasthenia gravis can severely impact a person's quality of life and ability to carry out daily tasks, such as speaking, chewing and swallowing food, or brushing teeth and hair. In some cases, patients may also experience difficulty breathing. I am hopeful for continued research advancements for new options to treat this debilitating disease."

Efgartigimod is currently under review with the U.S. Food and Drug Administration (FDA) for the treatment of gMG with a Prescription Drug User Fee Act (PDUFA) target action date of December 17, 2021. argenx also submitted and was notified of acceptance of an application for efgartigimod to Japan's Pharmaceuticals and Medical Devices Agency (PMDA) earlier this year.

Phase 3 ADAPT Trial

The Phase 3 ADAPT trial was a randomized, double-blind, placebo-controlled, multi-center, global trial evaluating the safety and efficacy of efgartigimod in patients with gMG. A total of 167 adult patients with gMG in North America, Europe and Japan enrolled in the trial and were treated. Patients were eligible to enroll in ADAPT regardless of antibody status, including patients with acetylcholine receptor (AChR) antibodies (AChR-Ab+) and patients where AChR antibodies were not detected. Patients were randomized in a 1:1 ratio to receive efgartigimod or placebo for a total of 26 weeks. ADAPT was designed to enable an individualized treatment approach with an initial treatment cycle followed by a variable number of subsequent treatment cycles. The primary endpoint was the number of AChR-Ab+ patients who achieved a response on the MG-ADL score defined by at least a two-point improvement for four or more consecutive weeks.

About Efgartigimod

Efgartigimod is an investigational 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.

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.

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. argenx is also advancing several earlier stage experimental medicines within its therapeutic franchises. argenx has offices in Belgium, the United States, Japan, and Switzerland. For more information, visit www.argenx.com and follow us on LinkedIn.

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