argenx Presents Additional Efgartigimod Data from Global Phase 3 ADAPT Trial at the Myasthenia Gravis Foundation of America 2020 Scientific Session

- New data consistent with positive topline results showing rapid and clinically meaningful responses to efgartigimod and safety profile comparable to placebo
- Biologics License Application on track to be submitted to U.S. Food and Drug Administration by end of 2020

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Breda, the Netherlands / Ghent, Belgium – argenx (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer, today announced the presentation of new data from the pivotal Phase 3 ADAPT trial evaluating efgartigimod for the treatment of patients with generalized myasthenia gravis (gMG). The presentation took place on Saturday, October 3, 2020 at the Myasthenia Gravis Foundation of America (MGFA) 2020 Virtual Scientific Session. argenx previously reported positive topline results from ADAPT in May 2020.

“Myasthenia gravis can be a very debilitating and potentially life-threatening chronic disease in patients leading to impairments that affect a patient’s ability to complete normal daily activities, including walking, swallowing, chewing food, talking or breathing easily. Efgartigimod demonstrated in ADAPT that it is well-tolerated and that patients can experience clinically meaningful improvements in key measures of function and strength following treatment, including, in some, the achievement of minimal symptom expression. These exciting results suggest that efgartigimod as a new potential therapy for gMG patients could have a real impact on some of the daily limitations that patients face,” commented James F. Howard Jr., M.D., Professor of Neurology (Neuromuscular Disease), Medicine and Allied Health, Department of Neurology, The University of North Carolina at Chapel Hill School of Medicine and principal investigator for the ADAPT trial.

Highlights of New Data Presented at MGFA 2020 Virtual Scientific Session

Magnitude of response: Substantial proportion of efgartigimod-treated acetylcholine receptor-antibody positive (AChR-Ab+) patients showed benefit at increasing thresholds on the Myasthenia Gravis Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scores compared to placebo patients at week four (one week after first treatment cycle).

- At least half of efgartigimod-treated patients showed a five-point or greater improvement on the MG-ADL score (55.6%) and a six-point or greater improvement on the QMG score (50.0%)
- One third (33.9%) of efgartigimod-treated patients showed a nine-point or greater improvement on the QMG score compared to zero patients on placebo

Repeatability of response: Similar proportion of efgartigimod-treated AChR-Ab+ patients were MG-ADL responders in the first (67.7% efgartigimod versus 29.7% placebo) and second (70.6% efgartigimod versus 25.6% placebo) treatment cycles ($p<0.0001$ for both cycles)

- In efgartigimod-treated patients, mean change from cycle baseline in total MG-ADL score at week four was 4.6 in cycle one and 5.1 in cycle two
- 78.5% (51/65) of efgartigimod-treated patients were MG-ADL responders across treatment cycles one and two

Clinical benefit in seronegative patients: Inclusion of QMG score in responder analysis showed further evidence of activity in patients where AChR antibodies were not detected (AChR-Ab-)

- 52.6% (10/19) of efgartigimod-treated patients were responders on the QMG score compared to 36.8% (7/19) of placebo patients
- Post-hoc analysis showed that 47.4% (9/19) of efgartigimod-treated patients were responders on both the QMG and the MG-ADL scores compared to 21.1% (4/19) of placebo patients

Key pharmacodynamic parameters: Total IgG and pathogenic autoantibody levels were reduced in efgartigimod-treated AChR-Ab+ patients throughout observation period, supporting proposed mechanism of action

- Mean maximum reductions at week four were 61.3% for total IgG and 57.6% for AChR-Ab
- Reductions similar across IgG subtypes and in overall population (AChR-Ab+ and AChR-Ab-)
- No reduction in albumin levels

Key Topline Data Previously Reported from ADAPT

Topline data from ADAPT were reported in May 2020. The trial met its primary endpoint showing 67.7% of efgartigimod-treated AChR-Ab+ gMG patients were responders on the MG-ADL score compared to 29.7% of placebo patients ($p<0.0001$). Responders were defined by having at least a 2-point change on the MG-ADL for at least four consecutive weeks. Efgartigimod was demonstrated to be well-tolerated with a safety profile that was comparable to placebo.

- 63.1% of AChR-Ab+ patients were responders to efgartigimod compared with 14.1% on placebo on the QMG score ($p<0.0001$); responder defined as having at least a three-point improvement for at least four consecutive weeks.
- 40.0% of efgartigimod-treated AChR-Ab+ patients achieved minimal symptom expression (MG-ADL scores of 0 (symptom free) or 1)

as a result of one treatment cycle, compared to 11.1% treated with placebo (p<0.0001).

- 84.1% of patients who were MG-ADL responders (37/44) had an onset of effect within the first two weeks
- In AChR-Ab+ patients who met the primary endpoint, the majority showed a sustained response, including 88.6% who achieved a response for at least six weeks, 56.8% for at least eight weeks and 34.1% for at least 12 weeks

“These new data on the magnitude and repeatability of response continue to support the potential of efgartigimod as a meaningful treatment for gMG patients. ADAPT was also a broad trial which included patients with acetylcholine receptor antibodies present and those without. We were pleased to show in this presentation proof of activity in the antibody-negative patients who are often left out of clinical trials,” commented Wim Parys, M.D., Chief Medical Officer of argenx. “It is particularly gratifying to present these favorable new data at the MGFA Virtual Scientific Session, a scientific meeting solely focused on addressing unmet needs for people living with gMG. We look forward to submitting our Biologics License Application for efgartigimod to the U.S. Food and Drug Administration before the end of the year with the goal to have efgartigimod available to patients and physicians in 2021.”

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 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 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 (MG)

MG is a rare and chronic autoimmune disease where IgG antibodies disrupt communication between nerves and muscles, 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. Patients with confirmed AChR antibodies account for 80-90% of the total gMG population. 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/.

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,” “estimates,” “anticipates,” “expects,” “intends,” “may,” “will” or “should” and include statements argenx makes concerning the timing of its BLA submission to the FDA and the availability of efgartigimod to patients and physicians and the therapeutic potential of its product candidates. 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 argenx’s expectations regarding its the inherent uncertainties associated with competitive developments, 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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