argenx Announces “GO” Decision in ADHERE Trial of Efgartigimod in Chronic Inflammatory Demyelinating Polyneuropathy Following Interim Analysis

Regulated Information/Inside Information

- Independent data monitoring committee confirmed go-forward decision based on evaluation of interim safety as well as efficacy assessments that surpassed pre-defined “GO” threshold
- 130 patients targeted for enrollment to support registrational program in CIDP
- Management to host conference call today at 2:30 p.m. CET (8:30 a.m. ET)

February 1, 2021

Breda, the Netherlands – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer, today announced its plan to continue enrollment in the ADHERE trial evaluating subcutaneous (SC) efgartigimod (co-formulated with Halozyme's ENHANZE® drug-delivery technology) in chronic inflammatory demyelinating polyneuropathy (CIDP). The ADHERE trial is expected to enroll approximately 130 patients to support potential registration of SC efgartigimod for the treatment of CIDP.

“Following our review of the interim ADHERE data and confirmation from the data monitoring committee, we are confident in our decision to continue with enrollment. We relied on key learnings from precedent CIDP trials in defining our go-forward thresholds and are excited to have cleared this first hurdle on the path to registration of efgartigimod in CIDP,” commented Wim Parys, M.D., Chief Medical Officer of argenx. “CIDP is now the fourth autoimmune disease that we selected based on its solid biological rationale where we have demonstrated clinical proof-of-concept, further emphasizing the broad applicability of efgartigimod. We hope to be able to offer a new potential treatment to CIDP patients who have limited therapeutic options for this severe, progressive disease.”

The “GO” decision was based on a planned efficacy and safety assessment following the enrollment of 30 patients into the initial part of the ADHERE trial. The interim analysis achieved the pre-defined threshold for continuation, which was based on response rates seen in precedent clinical trials of current standard of care in CIDP. The decision to continue enrollment was confirmed by an independent data monitoring committee. In addition, the tolerability profile observed to date is consistent with that of efgartigimod in other clinical trials.

The company will host a conference call today at 2:30 p.m. CET (8:30 a.m. ET) to discuss the decision to continue enrollment in ADHERE.

Dial-in numbers:
Please dial in 15 minutes prior to the live call.

Belgium	0800 389 13
France	0805 102 319
Netherlands	0800 949 4506
United Kingdom	0800 279 9489
United States	1 844 808 7140
International	1 412 902 0128

A live webcast of the presentation will be available on the Company’s website at www.argenx.com. A replay of the webcast will be available for approximately 1 year following the presentation.

ADHERE Trial Design

The ADHERE trial is a randomized, withdrawal study evaluating 1000mg weekly subcutaneous (SC) efgartigimod for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP). The trial consists of an open-label Stage A followed by a randomized, placebo-controlled Stage B with a planned interim responder analysis after the first 30 patients enroll in Stage A. In order to enter Stage A and receive efgartigimod, both patients who were treatment-naïve or on therapy must first receive a confirmed diagnosis of CIDP by an independent panel of experts and demonstrate active disease. To show active disease, patients who are on current CIDP therapy have to demonstrate a minimal clinically meaningful worsening after treatment withdrawal based on at least one CIDP clinical assessment tool, including INCAT, iRODS, or mean grip strength. To advance to Stage B, patients need to demonstrate a minimal clinically meaningful response to efgartigimod equivalent with the loss observed on the same efficacy scale on which worsening is observed during the withdrawal period. In Stage B, patients are randomized to either SC efgartigimod or placebo for up to 48 weeks. The primary endpoint is event-driven and based on the adjusted INCAT efficacy score in Stage B.

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. The subcutaneous formulation of efgartigimod is co-formulated with Halozyme's ENHANZE® drug delivery technology and is administered as a 1000mg weekly single injection.

About CIDP

Chronic inflammatory demyelinating polyneuropathy (CIDP) is a rare and serious autoimmune disease of the peripheral nervous system. Although confirmation of disease pathophysiology is still emerging, there is increasing evidence that IgG antibodies play a key role in the damage to the peripheral nerves. People with CIDP experience fatigue, muscle weakness and a loss of feeling in their arms and legs that can get worse over time or may come and go. These symptoms can significantly impair a person's ability to function in their daily lives. Without treatment, one-third of people living with CIDP will need a wheelchair.

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.

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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, estimates, anticipates, expects, intends, may, will, or should, and include statements argenx makes concerning the preliminary analysis of the ADHERE trial and its plans to continue enrollment of the ADHERE trial; the therapeutic potential of its product candidates; the intended results of its strategy; including the timing, design and outcome of the ADHERE clinical trial. 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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