argenx Advances Clinical Development of Efgartigimod in Primary Sjogren's Disease

RHO study supports proof-of-concept in primary Sjogren's disease

Decision informed by favorable safety profile and consistency across efficacy and biomarker measures

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Amsterdam, the Netherlands – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced its plan to continue the development of efgartigimod to Phase 3 in adults with primary Sjogren's disease (SjD), following the analysis of topline data from the Phase 2 RHO study. Detailed results will be presented at a future medical meeting.

"We are excited to be advancing efgartigimod's development in Sjogren's disease based on the totality of the data generated from the RHO study," said Luc Truyen, M.D., Ph.D., Chief Medical Officer of argenx. "Consistent with our indication selection strategy, we confirmed our IgG biology hypothesis with these data, and now have a demonstrated clinical effect across multiple efficacy scales to support proof-of-concept. Sjogren's disease can be debilitating, predominantly affects women, and given its heterogeneous nature, is often misdiagnosed with its symptoms poorly understood. With no current approved therapies to treat the underlying disease, the unmet need is substantial, and we recognize the opportunity to advance a new potential alternative treatment to these patients."

The decision to advance the clinical development of efgartigimod in SjD was supported by the safety, efficacy and biomarker results from the study. The observed safety and tolerability profile was consistent with other clinical trials. Efficacy assessments showed a treatment effect across multiple clinical endpoints, which were also consistent with biomarker data.

RHO Study Design

The Phase 2 RHO study was a randomized, double-blinded, placebo-controlled multicenter proof of concept study to evaluate the safety and efficacy of VYVGART in adults with SjD. In order to enter the study, patients needed to test positive for anti-Ro autoantibodies and maintain residual salivary flow. Thirty four patients were randomized 2:1 to receive either efgartigimod or placebo for up to 24 weeks. Multiple endpoints and biomarkers were evaluated in the signal-finding study, including the primary endpoint of CRESS (Composite of Relevant Endpoints for Sjogren's Syndrome). Within CRESS there are five components spanning: systemic disease activity as measured by the ESSDAI (EULAR Sjogren's Syndrome Activity Index), patient reported outcomes as measured by the ESSPRI (EULAR Sjogren's Syndrome Patient Reported Index), tear and salivary gland function and serology. To be a CRESS responder, patients needed to demonstrate a clinically meaningful benefit in at least 3 of the 5 composite items. Additional datapoints

were gathered including the clinESSDAI, STAR (Sjogren's Tool for Assessing Response), biomarker data, and the change in lymphocytic infiltrate levels through parotid biopsies.

About Sjogren's Disease

Sjogren's Disease (SjD) is a chronic, slowly progressive inflammatory systemic autoimmune disease characterized by immune-mediated destruction of exocrine glands. SjD can be severely debilitating and have a negative impact on patient quality of life, with common symptoms reported as dry eyes and mouth, fatigue, joint point and impaired cognitive function. In addition, a substantial subset of patients suffer from extraglandular systemic disease. While the presence of anti-Ro and anti-LA IgG autoantibodies are considered a hallmark of disease, the underlying cause of SjD is believed to be multi-factorial, triggered by environmental factors, leading to auto-immunity and chronic inflammation. SjD predominantly impacts women with a 9:1 female:male incidence ratio. Given the heterogeneous nature of the disease, the treatment journey can be challenging with long delays and high rates of misdiagnosis. There are no FDA-approved treatments targeting the disease itself, leaving current treatments to focus primarily on individual symptom management.

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, in both an intravenous and subcutaneous (SC) formulation. Efgartigimod is marketed as VYVGART® for the treatment of generalized myasthenia gravis in more than 30 regions globally and immune thrombocytopenia in Japan.

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 approved neonatal Fc receptor (FcRn) blocker, globally in the U.S., Japan, Israel, the EU, the UK, China and Canada. The Company is evaluating efgartigimod in multiple serious autoimmune diseases and advancing several earlier stage experimental medicines within its therapeutic franchises. For more information, visit www.argenx.com and follow us on LinkedIn, X (formerly known as Twitter), and Instagram.

Media:

Ben Petok
bpetok@argenx.com

Investors:

Alexandra Roy (US)
aroy@argenx.com

Lynn Elton (EU)
lelton@argenx.com

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 "aims," "committed," "plan" or "potential" and include statements argenx makes concerning its plan to continue the development to Phase 3 of efgartigimod for adults with primary SjD; the potential impact of efgartigimod for SjD patients; the advancement of, and anticipated clinical developmentof efgartigimod's development in primary SjD and its goal of translating immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. 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 but not limited to, the results of argenx's clinical trials, expectations regarding the inherent uncertainties associated with development of novel drug therapies, preclinical and clinical trial and product development activities and regulatory approval requirements, the acceptance of our products and product candidates by our patients as safe, effective and cost-effective, and the impact of governmental laws and regulations on our business. 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 press release. 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.