



argenx Provides Update on Phase 3 UNITY Study of Efgartigimod SC in Sjögren's Disease

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Amsterdam, the Netherlands – argenx SE (Euronext & Nasdaq: ARGX), a global immunology innovation company, today announced that it will discontinue the Phase 3 UNITY study of efgartigimod subcutaneous (SC) (efgartigimod alfa and hyaluronidase-qvfc) in adults with moderate-to-severe Sjögren's disease.

The decision is based on the recommendation from an Independent Data Monitoring Committee (IDMC) to stop the study for futility following an interim analysis. The IDMC concluded that the UNITY study is unable to meet its primary endpoint. Safety was consistent with efgartigimod's established profile and no new safety signals were identified.

"We are disappointed by this outcome, most of all for people living with Sjögren's disease, who are still waiting for treatments that fundamentally change the course of their disease," said Luc Truyen, M.D., Ph.D., Chief Medical Officer at argenx. "Sjögren's Disease is one of the most heterogeneous and complicated diseases in immunology, and unraveling the biology of complex diseases is at the heart of what we do. We will analyze these data in depth and share what we learn with the Sjögren's community. We are grateful to the patients, families, investigators and site staff who made this study possible."

Following study close and database lock, argenx will conduct a comprehensive analysis of the data to understand the study's outcome and generate insights that may inform future research in Sjögren's disease.

UNITY Study Design

UNITY is a Phase 3, randomized, double-blind, placebo-controlled, multicenter study with an open-label extension, designed to evaluate the efficacy, safety and tolerability of efgartigimod SC in adults with moderate-to-severe Sjögren's disease. To be eligible, patients had to meet the 2016 ACR/EULAR classification criteria for primary Sjögren's disease, test positive for anti-Ro/SSA autoantibodies and have moderate-to-severe systemic disease activity (clinESSDAI ≥ 6) while receiving stable background standard of care. Patients were randomized 1:1 to receive weekly efgartigimod SC or placebo during the double-blind treatment period. The primary endpoint was change from baseline in systemic disease activity, as measured by the clinical EULAR Sjögren's Syndrome Disease Activity Index (clinESSDAI), at Week 48. Key secondary endpoints included the proportion of patients achieving low disease activity (clinESSDAI < 5), responder status on the Sjögren's Tool for Assessing Response (STAR), change in patient-reported symptoms as measured by the Diary of Sjögren's Symptoms Assessment (DiSSA), and safety and tolerability.

About Sjögren's Disease

Sjögren's disease is a chronic, slowly progressive, inflammatory systemic autoimmune disease characterized by immune-mediated destruction of the exocrine glands. It can be severely debilitating and have a negative impact on patient quality of life, with commonly reported symptoms including dry eyes and mouth, fatigue and joint pain. In addition, a substantial subset of patients suffer from extraglandular systemic disease. While the presence of anti-Ro and IgG autoantibodies is considered a hallmark of the disease, its underlying cause is believed to be multifactorial, with environmental triggers leading to autoimmunity and chronic inflammation. The disease predominantly affects women, with a 9:1 female-to-male incidence ratio. Given its heterogeneous nature, the treatment journey can be challenging, with long delays and high rates of misdiagnosis.

About VYVGART

VYVGART® (efgartigimod alfa fcab) is a first-in-class human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG autoantibodies. VYVGART Hytrulo® is a subcutaneous combination of efgartigimod alfa (VYVGART) and recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology to facilitate subcutaneous injection delivery of biologics.

VYVGART is approved for generalized myasthenia gravis (gMG) and immune thrombocytopenia (Japan only). VYVGART Hytrulo is approved for gMG and chronic inflammatory demyelinating polyneuropathy (CIDP). VYVGART Hytrulo may be marketed under different proprietary names in other regions.

About argenx

argenx is a global immunology innovation 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 and is evaluating its broad potential in multiple serious autoimmune diseases while advancing several earlier stage experimental medicines within its therapeutic franchises. For more information, visit www.argenx.com, and follow us on [LinkedIn](#), [Instagram](#), [Facebook](#), and [YouTube](#).

This press release contains inside information within the meaning of Article 7(1) of the EU Market Abuse Regulation (Regulation 596/2014).

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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 generally can be identified by the use of forward-looking words, such as “aim”, “anticipate”, “aspire”, “believe”, “can”, “continue”, “could”, “estimate”, “expect”, “entail”, “forecast”, “future”, “goals”, “hope”, “intend”, “is designed to”, “likely”, “may”, “might”, “objective”, “plan”, “possible”, “potential”, “pursue”, “project”, “predict”, “seek”, “should”, “strategy”, “target”, “will” and other words and terms of similar meaning and expression, including in connection with any discussion of future operating or financial performance. 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; uncertainties associated with the development of novel drug therapies; preclinical and clinical trial and product development risks and setbacks; interpretation of argenx’s clinical trial data by regulatory authorities and argenx’s ability to obtain regulatory approval; the risk that early stage clinical trials may not be predictive of results in later stage or large scale clinical trials; the occurrence of adverse safety events or participant dropouts; the acceptance of its products and product candidates by its patients as safe, effective, and cost-effective; the impact of governmental laws and regulations, including tariffs, export controls, sanctions and other regulations on its business; the impact of healthcare regulations, including rules on reimbursement for argenx’s products; competition in drug discovery, development and commercialization efforts; its reliance on third-party suppliers, service providers and manufacturers; and instability and conflicts in the regions in which the company has suppliers or markets for its products. A further list and description of these and other risks, uncertainties, and factors that could cause actual results to differ materially from those referred to in the forward-looking statements 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 risks and uncertainties, the reader is advised not to place 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.