argenx Provides Update on UplighTED Studies of Efgartigimod SC in Thyroid Eye Disease

December 15, 2025

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 that the Phase 3 UplighTED studies evaluating efgartigimod subcutaneous (SC) (efgartigimod alfa and hyaluronidase-qvfc) in adults with moderate to severe thyroid eye disease (TED) will be discontinued.

The decision is based on the recommendation from an Independent Data Monitoring Committee (IDMC) to stop the trials for futility following its review of data from a pre-specified interim analysis. Importantly, efgartigimod showed a favorable safety and tolerability profile, and no new safety signals were identified.

"We are disappointed the studies did not meet our desired outcome and we especially empathize with patients who are living with TED and seeking new therapies for this challenging disease," said Luc Truyen, M.D., Ph.D., Chief Medical Officer at argenx. "We had pre-planned this futility analysis as it provides a meaningful interim evaluation of observed patient outcomes and enables us to responsibly evaluate the study's future likelihood of success. This approach is fundamental to our disciplined and responsible stewardship of investment and resources in our clinical development programs. We are deeply grateful to the TED community and all those who contributed to these studies."

The IDMC conducted a futility evaluation of unblinded data from patients completing 24 weeks in the Phase 3 studies. Following close out and database lock, argenx will conduct a comprehensive analysis of the data to enhance understanding of the studies' outcomes and uncover key biological insights that may inform future research in TED. Data from the studies will be shared at a future medical meeting.

UplighTED Study Design
The Phase 3 randomized, double-masked, placebo-controlled, multicenter studies are designed to evaluate the efficacy, safety, tolerability, pharmacokinetics, pharmacodynamics, and immunogenicity of efgartigimod PH20 SC administered by prefilled syringe in adult participants with thyroid eye disease. Enrolled participants have active, moderate-to-severe thyroid eye disease associated with autoimmune thyroid conditions (Graves' disease or Hashimoto's thyroiditis). Patients were randomized in a 2:1 ratio to receive efgartigimod PH20 SC or placebo PH20 SC, respectively during the double-blinded treatment period. The primary endpoint is measured as the percentage of participants who were proptosis responders at week 24. Key secondary endpoints include change in proptosis measurement in the study eye from baseline up to week 24, change in the total Graves' Orbitopathy Quality of Life (GO-QoL) score from baseline up to week 24, and percentage of participants with resolution of diplopia at week 24.

About Thyroid Eye Disease (TED)
Thyroid Eye Disease (TED) is an autoimmune orbital disease associated with Graves' disease and other autoimmune thyroid pathologies such as Hashimoto's thyroiditis. TED is characterized by extraocular muscle enlargement, orbital adipose tissue expansion, and orbital inflammation, which can lead to proptosis, diplopia, or vision loss in severe cases. Persistent orbital symptoms often impair patient quality of life. In the active phase, swelling and protrusion can cause pain and may affect vision. In the inactive phase, some symptoms may improve; however, protrusion and double vision may persist.

About VYVGART and VYVGART SC
VYVGART® (efgartigimod alfa fcab) is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG autoantibodies. It is the first approved FcRn blocker for the treatment of generalized myasthenia gravis (gMG) and chronic inflammatory demyelinating polyneuropathy (CIDP) globally, and for primary immune thrombocytopenia (ITP) in Japan. VYVGART SC is a subcutaneous combination of efgartigimod alfa and recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE ®drug delivery technology to facilitate subcutaneous injection delivery of biologics. It is marketed as VYVGART® Hytrulo in the U.S., VYVGART SC in Europe, VYVDURA® in Japan, and may be marketed under different proprietary names following approval in other regions.

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

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 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.

Media:
Colin McBean
cmcbean@argenx.com

Investors:
Alexandra Roy
aroy@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 “aim,” “committed,” “may,” “plan,” and “will” and include statements argenx makes concerning its future analysis of the data from the Phase 3 UplighTED studies to enhance understanding of the studies’ outcomes and uncover key biological insights that may inform future research in TED; the sharing of the data from the Phase 3 UplighTED studies at a future medical meeting; its commitment to improving the lives of people suffering from severe autoimmune diseases; 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 the development of novel drug therapies; preclinical and clinical trial and product development activities and regulatory approval requirements; 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; its reliance on third-party suppliers, service providers and manufacturers; inflation and deflation and the corresponding fluctuations in interest rates; and regional instability and conflicts. 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.