argenx Reports Topline Results from ADVANCE-SC Study of VYVGART Hytrulo in Primary Immune Thrombocytopenia

- Study did not meet primary or secondary endpoints
- Favorable safety and tolerability profile consistent with previous clinical trials
- Conference call scheduled for today, November 28, 2023 at 8:30am ET (2:30pm CET)

Regulated information – Inside information

November 28, 2023, 7:00am CET

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 topline results from the ADVANCE-SC study evaluating VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) in adults with primary immune thrombocytopenia (ITP). The study did not meet the primary endpoint of a sustained platelet count response in chronic ITP patients.

Additional analyses of the dataset are ongoing and the full results will be presented at an upcoming medical meeting and in a peer-reviewed publication.

"This is not the outcome we had hoped for patients, but setbacks are part of pioneering a new class of medicines and these data will provide insights into the broader understanding of FcRn and ITP," said Luc Truyen, M.D., Ph.D., Chief Medical Officer of argenx. "We are very grateful to everyone involved in the ADVANCE-SC study, especially the patients and their families, the investigators, and our internal team who worked tirelessly to complete this global study. We remain committed to the ITP patient community who urgently needs additional treatment options to manage this challenging disease, and continue to move forward in our deeper analysis of these results."

ADVANCE-SC Study Data

ADVANCE-SC is the second of two registrational trials conducted as part of the ongoing ITP development program for VYVGART and enrolled 207 adult patients with chronic and persistent ITP. Patients were heavily pre-treated and 75% of patients had received three or more prior ITP therapies.

- Primary endpoint was not met (p=0.5081); 13.7% (17/124) of treated patients demonstrated a sustained platelet count response compared to 16.2% (11/68) of placebo patients
- Secondary endpoints were not met, including additional endpoints on International Working Group (IWG) responder status and mean platelet count change from baseline

- VYVGART Hytrulo was well-tolerated in ADVANCE-SC; the observed safety and tolerability profile was consistent with ADVANCE-IV and the confirmed safety profile of VYVGART and VYVGART Hytrulo

Results from the first study in the ITP registrational program, ADVANCE-IV, were reported in May 2022. The study met its primary and key platelet-derived secondary endpoints. ADVANCE-IV formed the basis of the regulatory submission for approval of VYVGART IV for ITP in Japan, where a decision is expected in the first quarter of 2024.

VYVGART is currently being evaluated in 13 severe autoimmune diseases, including the registrational ADDRESS study for pemphigus from which topline results are expected around year-end 2023.

Conference Call Details
argenx will host a conference call today at 2:30 pm CET (8:30am ET) to discuss the ADVANCE-SC results. A webcast of the live call and replay may be accessed on the Investors section of the argenx website.

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

Belgium	32 800 50 201
France	33 800 943355
Netherlands	31 20 795 1090
United Kingdom	44 800 358 0970
United States	1 888 415 4250
Japan	81 3 4578 9081
Switzerland	41 43 210 11 32

About the ADVANCE-SC Study

The ADVANCE-SC trial was a randomized, double-blind, placebo-controlled, multicenter, global trial evaluating the efficacy and safety of VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) in adult patients with chronic or persistent primary ITP. Enrolled patients had a confirmed ITP diagnosis and a mean entry platelet count of less than $30x10^9$/L. Patients were on a stable dose of at least one ITP treatment prior to randomization and had received at least one prior therapy. Concomitant medications permitted included corticosteroids, nonsteroidal immunosuppressive drugs, fostamatinib or TPO-RAs. The study patients who were on 'watch and wait' at baseline were required to have received at least 2 prior treatments for ITP.

Patients were randomized in a 2:1 ratio to receive VYVGART Hytrulo or placebo for a total of 24 weeks as part of the primary trial. The primary endpoint was measured by the proportion of patients with chronic ITP with a sustained platelet count response defined as achieving platelet counts of greater than or equal to $50x10^9$/L for at least four of the last six scheduled visits between weeks 19 and 24. Patients who received rescue therapy at week 12 or later, or for whom dose and/or frequency of concurrent ITP therapies increased at week 12 or later, were considered non-responders. Key

secondary endpoints included extent of disease control over 24-week treatment period, proportion of overall population with sustained platelet count response, an extended primary endpoint analysis between weeks 17 and 24, and the incidence and severity of WHO-classified bleeding events.

About Immune Thrombocytopenia (ITP)

Immune thrombocytopenia (ITP) is an autoimmune disorder where immunoglobulin G (IgG) autoantibodies destroy platelets and reduce platelet production, which can lead to an increased risk of excessive bleeding and bruising. In rare cases, ITP can lead to severe anemia and life threatening gastrointestinal or intracranial hemorrhages. ITP is also associated with debilitating fatigue and significant impacts on mental health, including anxiety, fear and depression. Many ITP patients are inadequately controlled on current therapies so a significant unmet need exists for additional treatment options.

About VYVGART Hytrulo

VYVGART Hytrulo is a subcutaneous combination of efgartigimod alfa, a human IgG1 antibody fragment marketed for intravenous use as VYVGART®, and recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology to facilitate subcutaneous injection delivery of biologics. In binding to the neonatal Fc receptor (FcRn), VYVGART Hytrulo results in the reduction of circulating IgG.

VYVGART Hytrulo is the proprietary name in the U.S. for subcutaneous efgartigimod alfa and recombinant human hyaluronidase PH20. It is marketed in Europe as VYVGART and may be marketed under different proprietary names following approval in other regions.

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 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, Twitter, and Instagram.

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

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," "believes," "hope," "estimates," "anticipates," "expects," "intends," "may," "will," "should," or "commitment" and include statements argenx makes concerning argenx' topline results from the ADVANCE-SC study of VYVGART Hytrulo in ITP, its commitment to the ITP patient community, its commitment to bringing VYVGART IV to ITP patients in Japan, where the regulatory review is ongoing based on the success of its first trial, and the expected timing of such regulatory review decision, the expected timing of the topline results for the registrational ADDRESS study, 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 argenx's additional analyses of the dataset from the ADVANCE-SC study of VYVGART Hytrulo in ITP, expectations regarding the inherent uncertainties associated with development of novel drug therapies, preclinical and clinical trial and product development activities and regulatory approval requirements, including the approval of VYVGART IV for ITP patients in Japan and the topline results of the registrational ADDRESS study for pemphigus, 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 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