

## **argenx Reports Positive Topline Data from ADHERE Study of VYVGART Hytrulo in Patients with Chronic Inflammatory Demyelinating Polyneuropathy**

- Study met primary endpoint ( $p=0.000039$ ); VYVGART® Hytrulo demonstrated 61% reduction (HR: 0.39 95% CI: 0.25; 0.61) in risk of relapse versus placebo
- IgG autoantibodies shown to play significant role in underlying CIDP disease biology
- Favorable safety and tolerability profile consistent with previous clinical trials and confirmed safety profile of VYVGART®
- Conference call scheduled for today, July 17, 2023 at 8:30am ET (2:30pm CET)

### **Regulated information – Inside information**

**Amsterdam, The Netherlands – July 17, 2023** – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced positive topline results from the ADHERE study evaluating VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) in adults with chronic inflammatory demyelinating polyneuropathy (CIDP). The study met its primary endpoint ( $p=0.000039$ ), demonstrating a significantly lower risk of relapse with VYVGART Hytrulo compared to placebo. Detailed data from ADHERE will be presented at an upcoming medical meeting.

#### **ADHERE Highlights**

- Primary endpoint met ( $p=0.000039$ ); VYVGART Hytrulo demonstrated 61% reduction (HR: 0.39 95% CI: 0.25; 0.61) in the risk of relapse versus placebo
- 67% of patients in open-label Stage A demonstrated evidence of clinical improvement (ECI), indicating that IgG autoantibodies play a significant role in the underlying biology of CIDP
- Safety and tolerability profile consistent with confirmed safety profile of VYVGART
- 91% (226/249) of eligible patients continued to the ADHERE-Plus open-label extension study

"CIDP is a chronic, progressive autoimmune disease that can cause substantial disability in those affected, often leading to impaired ambulation or difficulty completing normal daily tasks without help. The positive ADHERE data show that VYVGART Hytrulo may represent a new patient-forward treatment option that can prevent symptom deterioration while minimizing side effects and treatment burden," commented Jeffrey Allen, M.D., Associate Professor, Department of Neurology, University of Minnesota. "With ADHERE, argenx has set a new standard for innovative CIDP studies that more broadly inform the neuromuscular community. The findings from the trial indicate we may have a novel weapon to combat this debilitating condition in our ongoing efforts to improve the lives of individuals affected by CIDP."

“People living with CIDP often experience significant challenges with daily function including fatigue, numbness, tingling, pain and weakness while facing a future with limited mobility or independence. The promising ADHERE data bring hope to the CIDP community of a brighter future where they could experience more positive moments doing the things that make them most happy,” said Lisa Butler, Executive Director of the GBS-CIDP Foundation International.

“With these positive ADHERE data, we have generated strong clinical evidence that CIDP has a significant IgG-driven pathogenesis component and that VYVGART Hytrulo can meaningfully improve and stabilize disease symptoms with a favorable safety profile and a simple route of administration,” commented Luc Truyen, M.D., Ph.D., Chief Medical Officer of argenx. “We are very grateful to the patients participating in the ADHERE trial and their supporters, the investigators, our collaborators and our argenx colleagues for the success of this innovative trial. Together, we are moving one step closer to transforming the treatment of autoimmunity.”

### **Detailed ADHERE Results**

ADHERE is the largest clinical trial of CIDP patients to date, enrolling adults who were treatment naïve (not on active treatment within the past six months) or currently on immunoglobulin therapy or corticosteroids. The trial consisted of a run-in period where current treatment was stopped followed by an open-label Stage A, after which responders to VYVGART Hytrulo advanced to a randomized, placebo-controlled Stage B.

322 patients enrolled in Stage A and received treatment with VYVGART Hytrulo

- 67% (214/322) demonstrated evidence of clinical improvement (ECI) after a run-in withdrawal period based on the Inflammatory Neuropathy Cause and Treatment (INCAT) Disability Score, the Inflammatory Rasch-built Overall Disability Scale (I-RODS) or grip strength
- 70% (214/304) demonstrated ECI excluding patients ongoing in Stage A at the time of the 88<sup>th</sup> event who did not have the full opportunity to achieve a response
- 78% (214/275) demonstrated ECI in a sensitivity analysis of patients who received at least four injections to reach the full IgG-lowering effect of VYVGART Hytrulo
- Response rates similar across all prior CIDP medication subgroups with consistent efficacy on INCAT, I-RODS and grip strength.

221 responders from Stage A entered Stage B, where the primary endpoint was the relative risk of relapse based on time to relapse on the INCAT Disability Score

- VYVGART Hytrulo significantly reduced the risk of CIDP relapse compared to placebo
  - Primary endpoint was met ( $p=0.000039$ ); VYVGART Hytrulo demonstrated a 61% reduction (HR: 0.39 95% CI: 0.25; 0.61) in the risk of relapse compared to placebo based on time to the first adjusted INCAT deterioration of  $\geq 1$  point
  - VYVGART Hytrulo patients had a lower relapse rate compared to placebo at Week 24 (26% versus 54%) and Week 48 (34% versus 60%)

- VYVGART Hytrulo patients experienced longer time to relapse compared to those on placebo with a rapid separation of the Kaplan–Meier curves beginning at Week 4 and sustained through Week 48
- VYVGART Hytrulo patients demonstrated a clinically meaningful mean improvement of 7.7 points on I-RODS and 12.3kPa on grip strength in Stage A. This clinically meaningful benefit was maintained in Stage B by treated patients and lost in placebo patients.
- Clinical benefit observed across all efficacy scales and patient subgroups, regardless of prior therapy

VYVGART Hytrulo was well-tolerated with a safety profile that is consistent with prior clinical trials and the known profile of VYVGART. The most frequent treatment-related adverse event was injection site reactions (ISRs), which occurred in a lower percentage of patients than previous VYVGART Hytrulo trials (20% in Stage A; 10% in Stage B). All ISRs were mild to moderate and resolved over time.

### Conference Call Details

argenx will host a conference call today at 2:30pm CET (8:30am ET) to discuss the ADHERE 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 ADHERE Trial Design

The ADHERE trial was a multicenter, randomized, double-blind, placebo-controlled trial evaluating VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP). ADHERE enrolled 322 adult patients with CIDP who were treatment naïve (not on active treatment within the past six months or newly diagnosed) or being treated with immunoglobulin therapy or corticosteroids. The trial consisted of an open-label Stage A followed by a randomized, placebo-controlled Stage B. In order to be eligible for the trial, the diagnosis of CIDP was confirmed by an independent panel of experts. Patients entered a run-in stage, where any ongoing CIDP treatment was stopped and in order to be eligible for Stage A had to demonstrate active disease, with clinically meaningful worsening on at least one CIDP clinical assessment tool, including INCAT, I-RODS, or mean grip strength. Treatment naïve patients were able to skip the run-in period with proof of recent worsening. To advance to Stage B, patients needed to demonstrate evidence of clinical improvement (ECI) with VYVGART Hytrulo. ECI was achieved through improvement of the INCAT score, or improvement on I-

RODS or mean grip strength if those scales had demonstrated worsening during the run-in period. In Stage B, patients were randomized to either VYVGART Hytrulo or placebo for up to 48 weeks. The primary endpoint was measured once 88 total relapses or events were achieved in Stage B and was based on the hazard ratio for the time to first adjusted INCAT deterioration (i.e. relapse). After Stage B, all patients had the option to roll-over to an open-label extension study to receive VYVGART Hytrulo.

argenx has an exclusive license agreement with Zai Lab for the development and commercialization of VYVGART and VYVGART Hytrulo in Greater China. Through this agreement, Zai Lab recruited Chinese patients into the ADHERE trial.

### **About Chronic Inflammatory Demyelinating Polyneuropathy**

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 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. It is the first-and-only approved FcRn blocker administered by subcutaneous injection.

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

See Important Safety Information below and full [Prescribing Information](#) for VYVGART Hytrulo for additional information

### **Important Safety Information**

#### **What is VYVGART® HYTRULO (efgartigimod alfa and hyaluronidase-qvfc)?**

VYVGART HYTRULO is a prescription medicine used to treat a condition called generalized myasthenia gravis, which causes muscles to tire and weaken easily throughout the body, in adults who are positive for antibodies directed toward a protein called acetylcholine receptor (anti-AChR antibody positive).

### **IMPORTANT SAFETY INFORMATION**

## What is the most important information I should know about VYVGART HYTRULO?

VYVGART HYTRULO may cause serious side effects, including:

- **Infection.** VYVGART HYTRULO may increase the risk of infection. The most common infections for efgartigimod alfa-fcab-treated patients were urinary tract and respiratory tract infections. More patients on efgartigimod alfa-fcab vs placebo had below normal levels for white blood cell counts, lymphocyte counts, and neutrophil counts. The majority of infections and observed lower white blood cell counts were mild to moderate in severity. Your healthcare provider should check you for infections before starting treatment, during treatment, and after treatment with VYVGART HYTRULO. Tell your healthcare provider if you have any history of infections. Tell your healthcare provider right away if you have signs or symptoms of an infection during treatment with VYVGART HYTRULO such as fever, chills, frequent and/or painful urination, cough, pain and blockage of nasal passages/sinus, wheezing, shortness of breath, fatigue, sore throat, excess phlegm, nasal discharge, back pain, and/or chest pain. If a serious infection occurs, your doctor will treat your infection and may even stop your VYVGART HYTRULO treatment until the infection has resolved.
- **Undesirable immune reactions (hypersensitivity reactions).** VYVGART HYTRULO and efgartigimod alfa-fcab can cause the immune system to have undesirable reactions such as rashes, swelling under the skin, and shortness of breath. Hives were also observed in patients treated with VYVGART HYTRULO. In clinical studies, the reactions were mild or moderate and occurred within 1 hour to 3 weeks of administration, and the reactions did not lead to VYVGART HYTRULO discontinuation. Your healthcare provider should monitor you during and after treatment and discontinue VYVGART HYTRULO if needed. Tell your healthcare provider immediately about any undesirable reactions to VYVGART HYTRULO.

Before taking VYVGART HYTRULO, tell your healthcare provider about all of your medical conditions, including if you:

- Have a history of infection or you think you have an infection.
- Have received or are scheduled to receive a vaccine (immunization). Discuss with your healthcare provider whether you need to receive age-appropriate immunizations before initiation of a new treatment cycle with VYVGART HYTRULO. The use of vaccines during VYVGART HYTRULO treatment has not been studied, and the safety with live or live-attenuated vaccines is unknown. Administration of live or live-attenuated vaccines is not recommended during treatment with VYVGART HYTRULO.
- Are pregnant or plan to become pregnant and are breastfeeding or plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

## What are the common side effects of VYVGART HYTRULO?

The most common side effects of efgartigimod alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. Additional common side effects of VYVGART HYTRULO are injection site reactions, including rash, redness of the skin, itching sensation, bruising, pain, and hives.

These are not all the possible side effects of VYVGART HYTRULO. Call your doctor for medical advice about side effects. You may report side effects to the US Food and Drug Administration at 1-800-FDA-1088.

**Please see the full Prescribing Information for VYVGART HYTRULO and talk to your doctor.**

### **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 and China. 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](http://www.argenx.com) and follow us on [LinkedIn](#), [Twitter](#), and [Instagram](#).

**For further information, please contact:**

### **Media:**

Erin Murphy  
[emurphy@argenx.com](mailto:emurphy@argenx.com)

### **Investors:**

Alexandra Roy (US)  
[ARoy@argenx.com](mailto:ARoy@argenx.com)

Lynn Elton (EU)  
[LElton@argenx.com](mailto: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 “may,” “will,” or “should” and include those that argenx makes concerning the benefits and safety profile of VYVGART and VYVGART Hytrulo; the expected availability of VYVGART Hytrulo; the safety profile and efficacy signals from the ADHERE study; and the prospects of VYVGART Hytrulo as a treatment for chronic inflammatory demyelinating polyneuropathy (“CIDP”), including its ability to transform CIDP treatment for patients and the therapeutic potential and patient treatment experience of VYVGART Hytrulo for the treatment of CIDP. 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. 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.