

argenx Announces Publication in *The Lancet Neurology* of Pivotal ADHERE Study Data in Chronic Inflammatory Demyelinating Polyneuropathy

ADHERE was largest and most innovative clinical trial of CIDP patients to date

VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) demonstrated reduction in disease progression, reduced risk of relapse and rapid onset of action

VYVGART Hytrulo is first and only neonatal Fc receptor (FcRn) blocker FDA-approved to treat CIDP

September 19, 2024 – 7:00 am 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 publication in *The Lancet Neurology* of the pivotal ADHERE Study, the largest clinical trial to date in chronic inflammatory demyelinating polyneuropathy (CIDP). CIDP is a rare, debilitating, often progressive, immune-mediated neuromuscular disorder of the peripheral nervous system. This is the first time the ADHERE Study has been published in a peer-reviewed medical journal. A link to the full manuscript can be found [here](#).

“Since its approval in June, VYVGART Hytrulo is already transforming the lives of patients with CIDP,” said Luc Truyen, M.D., Ph.D., Chief Medical Officer of argenx. “With today’s publication in *The Lancet Neurology*, we are also advancing scientific knowledge of the disease biology underlying CIDP and thereby helping to progress further innovation with the potential, like VYVGART Hytrulo, to significantly improve function for patients while easing the burdens associated with prior treatments.”

Highlights from the ADHERE study:

- ADHERE met its primary endpoint ($p < 0.0001$) demonstrating a 61% reduction (HR: 0.39 95% CI: 0.25; 0.61) in the risk of relapse versus placebo
- 69% (221/322) of patients treated with VYVGART Hytrulo, regardless of prior treatment, demonstrated evidence of clinical improvement, including improvements in mobility, function and strength
- 99% of trial participants elected to participate in the ADHERE open-label extension
- VYVGART Hytrulo was well-tolerated and safety results were consistent with the known safety profile of VYVGART in previous clinical studies and real-world use

The ADHERE data demonstrate that VYVGART Hytrulo has a rapid onset of action, and can reduce CIDP disease progression and risk of relapse:

- **Reduced risk of relapse:** VYVGART Hytrulo reduced the risk of relapse by 61% as assessed by aINCAT deterioration (Stage B primary endpoint) versus placebo (HR 0.394 [95% CI 0.253–0.614]; $p < 0.0001$).
- **Reduced disease progression:** VYVGART Hytrulo reduced the risk of CIDP disease progression based on time-to-first ≥ 4 -point decrease in I-RODS score compared with Stage B baseline (HR 0.537 [95% CI 0.354–0.814]; nominal $p = 0.0034$).
- **Rapid onset of action:** In Stage A, time to first improvement on aINCAT, I-RODS, or grip strength scores among the 25th percentile of patients was 9.0 days (95% CI 8.0-9.0) after the first dose of VYVGART Hytrulo; the median estimate was 22.0 days (15.0-23.0).

In June 2024, the U.S. Food and Drug Administration approved VYVGART Hytrulo for the treatment of adult patients with CIDP. VYVGART Hytrulo is also approved for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

See FDA-approved Important Safety Information below and full Prescribing Information for VYVGART Hytrulo for additional information.

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

VYVGART HYTRULO is a prescription medicine used for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

IMPORTANT SAFETY INFORMATION

Do not use VYVGART HYTRULO if you have a serious allergy to efgartigimod alfa, hyaluronidase, or any of the other ingredients in VYVGART HYTRULO. VYVGART HYTRULO can cause serious allergic reactions and a decrease in blood pressure leading to fainting.

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. Signs or symptoms of an infection may include 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.

Allergic Reactions (hypersensitivity reactions). VYVGART HYTRULO can cause allergic reactions such as rashes, swelling under the skin, and shortness of breath. Hives were also observed in patients treated with VYVGART HYTRULO. Serious allergic reactions, such as trouble breathing and decrease in blood pressure leading to fainting have been reported with efgartigimod alfa-fcab.

Infusion-Related Reactions. VYVGART HYTRULO can cause infusion-related reactions. The most frequent symptoms and signs reported with efgartigimod alfa-fcab were high blood pressure, chills, shivering, and chest, abdominal, and back pain.

Tell your doctor if you have signs or symptoms of an infection, allergic reaction, or infusion-related reaction. These can happen while you are receiving your VYVGART HYTRULO treatment or afterward. Your doctor may need to pause or stop your treatment. Contact your doctor immediately if you have signs or symptoms of a serious allergic reaction.

Before taking VYVGART HYTRULO, tell your doctor if you:

- take any medicines, including prescription and non-prescription medicines, supplements, or herbal medicines,
- have received or are scheduled to receive a vaccine (immunization), or
- have any allergies or medical conditions, including if you are pregnant or planning to become pregnant, or are breastfeeding.

What are the common side effects of VYVGART HYTRULO?

The most common side effects in efgartigimod-alfa-fcab-treated patients were respiratory tract infection, headache, and urinary tract infection. Additional common side effects with 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 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.

About VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)

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.

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. There are approximately 24,000 patients in the U.S. currently receiving treatment for CIDP.

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, Canada 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 and follow us on [LinkedIn](#), [X/Twitter](#), [Instagram](#), [Facebook](#), and [YouTube](#).

Contacts

Media:

Ben Petok
bpetok@argenx.com

Investors:

Alexandra Roy (US)
aroy@argenx.com

Lynn Elton (EU)
lelton@argenx.com