



argenx Announces Approval of VYVDURA (efgartigimod alfa and hyaluronidase-qvfc) in Japan for Adults with Chronic Inflammatory Demyelinating Polyneuropathy

VYVDURA® now approved for at-home self-injection in Japan for both generalized myasthenia gravis and CIDP

argenx's VYVGART® and VYVDURA portfolio approved in Japan for three indications – first country globally with access across three indications

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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 Japan's Ministry of Health, Labour and Welfare (MHLW) approved VYVDURA for adults with chronic inflammatory demyelinating polyneuropathy (CIDP). VYVDURA is approved for CIDP as a once weekly 30-to-90 second subcutaneous injection, which can be self-administered at home, and is the first and only neonatal Fc receptor (FcRn) blocker approved for the treatment of CIDP.

"CIDP is a rare and debilitating disease for which there has been little innovation in treatment in 30 years," said Luc Truyen, M.D., Ph.D., Chief Medical Officer of argenx. "With VYVDURA, CIDP patients in Japan now have access to a novel therapy with a focused mode of action offering a convenient 30-to-90 second at-home self-injection option with an established efficacy and safety profile, as demonstrated by the ADHERE trial and real-world evidence. By extending the reach of this transformational therapy to thousands more patients, argenx continues to bring efgartigimod, our first-in-class FcRn blocker, to more patients in Japan and around the world suffering from severe autoimmune disease."

CIDP is a progressive, immune-mediated rare and debilitating neuromuscular disorder of the peripheral nervous system. Patients experience a range of disabling mobility and sensory issues, including trouble standing from a seated position, pain and fatigue, and frequent tripping or falling. Many patients become wheelchair bound and are unable to work as the disease progresses. Currently, 85% of patients require ongoing treatment and nearly 88% of treated patients experience residual impairment and disability.

The MHLW approval is based on the ADHERE Study, the largest clinical trial to date studying CIDP. In the ADHERE study, 69% (221/322) of patients treated with VYVDURA, regardless of prior treatment, demonstrated evidence of clinical improvement, including improvements in mobility, function and strength. 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. Ninety-nine percent of trial participants elected to participate in the ADHERE+ open-label extension. The safety results were generally consistent with the known safety profile of VYVDURA in previous clinical studies and real-world use.

VYVDURA was approved by the MHLW for manufacturing and marketing in January 2024 and launched in April 2024 for the treatment of generalized myasthenia gravis (gMG). In March 2024, VYVDURA was designated as an Orphan Drug for the treatment of CIDP by the MHLW.

See FDA-approved Important Safety Information below and full [Prescribing Information](#) for VYVDURA, which is marketed as VYVGART Hytrulo in the United States, 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 VYVDURA® (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 VYVDURA. 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 VYVDURA 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 VYVDURA.

About VYVDURA

VYVDURA 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), VYVDURA results in the reduction of circulating IgG. It is the first-and-only approved FcRn blocker administered by subcutaneous injection for the treatment of CIDP.

VYVDURA is the proprietary name in Japan for subcutaneous efgartigimod alfa and recombinant human hyaluronidase PH20. It is marketed under different proprietary names in other regions.

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 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](#), [Twitter](#), and [Instagram](#).

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