argenx Announces FDA Approval of VYVGART Hytrulo for Chronic Inflammatory Demyelinating Polyneuropathy

VYVGART® Hytrulo is first and only neonatal Fc receptor (FcRn) blocker approved to treat chronic inflammatory demyelinating polyneuropathy (CIDP)

First novel, precision mechanism of action in more than 30 years for patients with CIDP

Third approved indication for VYVGART® and VYVGART Hytrulo franchise

Management to host conference call on June 21, 2024 at 11:00pm CET (5:00pm ET)

June 21, 2024, 4:40pm ET

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 U.S. Food and Drug Administration (FDA) has approved VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP). VYVGART Hytrulo is approved for CIDP as a once weekly 30-to-90 second subcutaneous injection. It is the first and only neonatal Fc receptor (FcRn) blocker approved for the treatment of CIDP.

“argenx continues to pursue our ambition to turn science into solutions for patients with severe autoimmunity,” said Luc Truyen M.D., Ph.D., Chief Medical Officer, argenx. “Patients have been waiting, and today argenx is delivering the first innovative treatment for CIDP in more than 30 years. VYVGART Hytrulo is a precision tool that has been shown to drive meaningful benefits for patients. Today’s FDA approval means that CIDP patients have a transformational new treatment option and further affirms the therapeutic profile of VYVGART Hytrulo and the potential of FcRn blockade in IgG-mediated autoimmune diseases.”

CIDP is a rare, debilitating, often progressive, immune-mediated 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.

“While CIDP patients face many daily concerns and challenges, fear of disease progression should not be one of them. CIDP can be debilitating and have significant impact on quality of life and many patients with CIDP require treatments that may be burdensome. The approval of this promising new treatment option for CIDP may provide hope to patients that they can treat their disease beyond just managing symptoms. CIDP patients deserve treatment options and we look forward to a future of choices for optimal and individualized care,” said Lisa Butler, Executive Director, GBS|CIDP Foundation.

“Today marks a groundbreaking day for the treatment of CIDP. Existing treatments have been limited to corticosteroids and plasma-derived therapies. These treatments, while effective for many patients, can be challenging for some patients to receive,” said Jeffrey Allen, M.D., Professor, Department of Neurology, University of Minnesota and Principal Investigator in the ADHERE trial. “Today’s approval of VYVGART Hytrulo gives doctors and patients a new, safe and effective treatment option that may lessen the burden of treatment that some patients experience.”

The FDA 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 VYVGART Hytrulo, 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 VYVGART in previous clinical studies and real-world use.

VYVGART Hytrulo is also approved in the U.S. for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Access to VYVGART Hytrulo

argenx is committed to supporting access for patients to its medicines and VYVGART Hytrulo is expected to be available for patients in the U.S. immediately. The typical patient will have an annual out-of-pocket cost similar to that of a VYVGART or VYVGART Hytrulo patient with gMG, or an IVIg patient with CIDP.

argenx has established a patient support program, My VYVGART Path, which can help patients and HCPs navigate access. My VYVGART Path program resources include disease and product education, access support and benefits verification, and financial assistance programs for eligible patients. More information is available at VYVGART.com.

Conference Call Details

argenx will host a conference call Friday, June 21, 2024, at 11:00 pm CET (5:00pm ET) to discuss the approval. A webcast of the live call and replay may be accessed on the Investors section of the argenx website.

Dial-in numbers:

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

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.
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.

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, Twitter, and Instagram.

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