argenx Announces FDA Acceptance of Supplemental Biologics License Application with Priority Review for VYVGART Hytrulo in Chronic Inflammatory Demyelinating Polyneuropathy

Prescription Drug User Fee Act (PDUFA) target action date is June 21, 2024

If approved, VYVGART® Hytrulo will be the first neonatal Fc receptor (FcRn) blocker to treat CIDP

February 20, 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 that the U.S. Food and Drug Administration (FDA) has accepted for priority review a supplemental Biologics License Application (sBLA) for VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP). The application has been granted a PDUFA target action date of June 21, 2024.

"Today's announcement brings us one step closer to delivering the transformative innovation of VYVGART Hytrulo to CIDP patients," said Luc Truyen, Chief Medical Officer of argenx. "CIDP is yet another example of an autoimmune disease that has not been well understood, and for which there has been insufficient innovation for patients. We chose to use a priority review voucher to accelerate review of our submission because CIDP patients have long been waiting for new treatment options. FDA's acceptance of the sBLA represents an important milestone in our continued drive to bring novel treatments for rare, autoimmune diseases, and a significant step forward for people whose lives have been profoundly impacted by this devastating disease."

The sBLA is supported by data from the ADHERE study, the largest clinical trial of CIDP to date, evaluating the safety and efficacy of subcutaneously administered VYVGART Hytrulo in adults with CIDP. The study met its primary endpoint (p=0.000039), demonstrating a 61% lower risk of relapse (HR: 0.39 95% CI: 0.25; 0.61) with VYVGART Hytrulo compared to placebo. In the open-label Stage A of the study, 67% of patients showed evidence of clinical improvement (ECI) following treatment with VYVGART Hytrulo. Given the mechanism of action of VYVGART Hytrulo as an FcRn blocker, the clinical results established that IgG autoantibodies play a significant role in the underlying biology of CIDP.

VYVGART Hytrulo was well-tolerated with a safety profile that is consistent with prior clinical trials and the known profile of VYVGART®. After completing ADHERE, 99% of eligible patients (226/228) continued to the ADHERE-+ open-label extension study.

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 (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.

See FDA-approved 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, 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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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 "plans," "aims," "believes," "continues," "hope," "estimates," "anticipates," "expects," "intends," "may," "will," "should," or "commitment" and include statements argenx makes concerning our advancement towards the delivery of VYVGART Hytrulo to CIDP patients, our continued drive to bring novel treatments for rare, autoimmune diseases, and our 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, the results of our PDUFA review for VYVGART Hytrulo to CIDP patients, expectations regarding the inherent uncertainties associated with development of novel drug therapies, preclinical and clinical trial and product development activities and regulatory approval requirements, 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.

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