argenx Announces Approval of VYVGART (efgartigimod alfa) in Japan for Adults with Primary Immune Thrombocytopenia

VYVGART® now approved in Japan for both generalized myasthenia gravis and primary immune thrombocytopenia (ITP)

Regulatory decision in Japan represents first global approval for VYVGART in ITP

March 26, 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 Japan's Ministry of Health, Labour and Welfare (MHLW) approved VYVGART (efgartigimod alfa) for intravenous (IV) use in adults with primary immune thrombocytopenia (ITP).

"argenx is on a mission to deliver transformative medicines for people living with severe autoimmune disease," said Tim Van Hauwermeiren, Chief Executive Officer of argenx. "We have always believed VYVGART has the potential to treat many IgG-mediated autoimmune diseases, and now patients in Japan, who have been waiting for a new treatment option, have one for ITP. My sincere thanks to all of those who contributed to today's milestone approval in Japan – it takes true collaboration to bring real innovation for the millions of patients around the world living with rare autoimmune disease. And our work has only just begun."

"ITP is a severe, debilitating autoimmune disease, and ITP patients typically experience a significantly lower quality of life," said Luc Truyen, M.D., Ph.D., Chief Medical Officer of argenx. "Physicians now treat ITP via a trial-and-error approach – or by cycling through current therapies. By reducing circulating autoantibodies, VYVGART is uniquely designed to serve as a precision intervention that targets the underlying disease biology of ITP. We are grateful to all of those who contributed to advancing our understanding of the disease so that we could bring VYVGART to patients in Japan."

The approval of VYVGART is based on results from the global Phase 3 ADVANCE-IV trial, which were published in the September 2023 issue of The Lancet. ADVANCE successfully met its primary endpoint, demonstrating that a higher proportion of chronic ITP patients receiving VYVGART achieved a sustained platelet count response compared to placebo. VYVGART demonstrated rapid onset of effect in chronic and persistent ITP patients, as well as a 51% response rate on the International Working Group (IWG) score, which is a measure developed by the world's leading experts on ITP and highly relevant to clinical care. Primary endpoint responders were observed across patient types regardless of age, disease severity, time since diagnosis, prior ITP treatment or background medication. VYVGART was well-tolerated in this 24-week study and the observed safety and tolerability profile was consistent with previous clinical trials.

Phase 3 ADVANCE Trial

The ADVANCE trial enrolled 131 adult patients with chronic and persistent ITP. Patients were heavily pretreated and 67% of patients had received three or more prior ITP therapies, including 59% who had prior thrombopoietin receptor agonist (TPO-RAs) experience, 34% with prior rituximab experience and 37% with a history of splenectomy. Patients were insufficiently controlled at baseline with mean platelet counts of $17x10^9$/L across all patients. Of patients who completed the full ADVANCE study, 94% (63/67) of VYVGART-treated patients and 97% (38/39) of placebo patients continued to the ADVANCE+ open-label extension study.

See the full Prescribing Information for VYVGART in the U.S., which includes the below Important Safety Information. For more information related to VYVGART in Japan, visit: argenx.jp.

What is VYVGART® (efgartigimod alfa-fcab)?
VYVGART 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
Do not use VYVGART if you have a serious allergy to efgartigimod alfa or any of the other ingredients in VYVGART. VYVGART can cause serious allergic reactions and a decrease in blood pressure leading to fainting.

VYVGART may cause serious side effects, including:

- **Infection.** VYVGART may increase the risk of infection. The most common infections 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 can cause allergic reactions such as rashes, swelling under the skin, and shortness of breath. Serious allergic reactions, such as trouble breathing and decrease in blood pressure leading to fainting have been reported with VYVGART.
- **Infusion-Related Reactions.** VYVGART can cause infusion-related reactions. The most frequent symptoms and signs reported with VYVGART 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 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, 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?
The most common side effects of VYVGART are respiratory tract infection, headache, and urinary tract infection. These are not all the possible side effects of VYVGART. 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 and talk to your doctor.

About Immune Thrombocytopenia

Immune thrombocytopenia (ITP) is an autoimmune disorder where immunoglobulin G (IgG) autoantibodies destroy platelets and reduce platelet production, which can lead to an increased risk of excessive bleeding and bruising. In severe cases, frequent bleeding events can cause anemia or even brain hemorrhage in rare cases. ITP is also associated with debilitating fatigue and significant impacts on mental health, including anxiety, fear and depression. Many ITP patients are inadequately controlled on current therapies so there remains a significant unmet need for additional treatment options.

About VYVGART® (efgartigimod alfa-fcab)

VYVGART is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG autoantibodies. It is the first approved FcRn blocker in the United States, EU and China for the treatment of adults with generalized myasthenia gravis (gMG) who are anti- acetylcholine receptor (AChR) antibody positive and in Japan for the treatment of adults with gMG who do not have sufficient response to steroids or non-steroidal immunosuppressive therapies (ISTs). VYVGART is being studied in adults with primary immune thrombocytopenia (ITP) and other IgG autoantibody-mediated diseases. VYVGART has been approved for adults with ITP only in Japan at this time.

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 “aims,” “believe,” “committed” or “potential” and include statements argenx makes concerning its mission to deliver transformative medicines for people living with severe autoimmune disease; its belief that VYVGART has the potential to treat many IgG-mediated autoimmune diseases such as ITP; the potential impact of VYVGART for ITP patients; and its 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 argenx’s clinical trials, 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.