argenx Announces Approval of VYVDURA® (efgartigimod alfa and hyaluronidase-qvfc) Injection for Subcutaneous Use in Japan for Generalized Myasthenia Gravis

2024年 1月 17日

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 ® (efgartigimod alfa and hyaluronidase-qvfc) injection for subcutaneous (SC) use for the treatment of adult patients with generalized myasthenia gravis (gMG), who do not have sufficient response to steroids or non-steroidal immunosuppressive therapies (ISTs). Following this decision, VYVGART is now approved in Japan for both intravenous (IV) and self-administered SC use.

"Today's approval of VYVDURA marks a significant milestone for the gMG community in Japan and furthers our commitment to deliver innovative treatments to autoimmune patients globally," said Hermann Strenger, General Manager, argenx Japan. "Bringing VYVDURA to Japan means there are now two formulations available for gMG patients, including the possibility to self-inject at home, allowing patients and their healthcare providers to choose the best option to meet their treatment needs."

The approval of VYVDURA is based on positive results from the Phase 3 ADAPT-SC study. ADAPT-SC established the efficacy of VYVDURA by demonstrating a reduction in percent change from baseline in total immunoglobulin G (IgG) levels comparable to VYVGART IV in adult gMG patients. ADAPT-SC was a bridging study to the Phase 3 ADAPT study, which formed the basis for approval of VYVGART in Japan in January 2022.

About the ADAPT-SC Trial

The Phase 3 ADAPT-SC trial was a multicenter, randomized, open-label, parallel-group study evaluating the noninferiority of the pharmacodynamic (PD) effect of VYVDURA compared with VYVGART in adult patients with gMG. The pharmacodynamic effect was measured by percent change from baseline for both total IgG and AChR autoantibody levels at day 29. Safety, clinical efficacy, immunogenicity and pharmacokinetics (PK) were also assessed. A total of 110 adult patients with gMG in North America, Europe and Japan enrolled in the ADAPT-SC trial. Patients were randomized in a 1:1 ratio to receive VYVDURA or VYVGART for one treatment cycle consisting of four doses at once-weekly intervals. The total study duration was approximately 12 weeks, including seven weeks of follow-up after the treatment cycle. At the completion of ADAPT-SC, patients had the opportunity to roll-over to ADAPT- SC+, an open-label extension study.

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. VYVGART SC was approved in the United States in June 2023 and is marketed as VYVGART® Hytrulo.

About Generalized Myasthenia Gravis

Generalized myasthenia gravis (gMG) is a rare and chronic autoimmune disease where IgG autoantibodies disrupt communication between nerves and muscles, causing debilitating and potentially life-threatening muscle weakness. Approximately 85% of people with MG progress to gMG within 24 months, where muscles throughout the body may be affected. Patients with confirmed AChR antibodies account for approximately 85% of the total gMG population.

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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