



argenx Announces U.S. Food and Drug Administration Approval of VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) Injection for Subcutaneous Use in Generalized Myasthenia Gravis

June 21, 2023

- VYVGART® Hytrulo is first FDA-approved subcutaneous (SC) injectable for generalized myasthenia gravis (gMG)
- With this approval, argenx broadens innovative gMG product offering and demonstrates continued commitment to providing more choice and flexibility for patients
- Efficacy of VYVGART Hytrulo was established by demonstrating a comparable pharmacodynamic (PD) effect to VYVGART® in Phase 3 ADAPT-SC bridging study
- Management to host conference call tomorrow at 2:30pm CET (8:30 am ET)

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) approved VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc). VYVGART Hytrulo is an injection for subcutaneous (SC) use for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. These patients represent approximately 85% of the total gMG population.

VYVGART Hytrulo is a subcutaneous product 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 delivery of biologics. The product is to be administered subcutaneously by a healthcare professional as a single injection (1,008 mg fixed dose) over 30-90 seconds in cycles of once weekly injections for four weeks.

"Today's approval of VYVGART Hytrulo is another significant milestone on our path to redefine what well-controlled means for gMG patients. The availability of a second argenx innovation in just 18 months also underscores our longstanding commitment to the gMG community by providing more choice and flexibility in how patients receive treatment," said Luc Truyen M.D., Ph.D., Chief Medical Officer, argenx. "With our broad gMG offering of both a first-in-class infusion and SC injection, we continue to offer an individualized treatment approach and possibility of staying symptom free, while providing patients options of how and where they want to seek treatment. We want to thank the gMG patient community and their supporters, clinical investigators, our employees and all stakeholders who have collaborated with us to advance this subcutaneous option, including our partners at Halozyme."

"The availability of another gMG treatment option from argenx, now in a subcutaneous delivery, is a meaningful advancement for the patient community. Patients now have the opportunity to receive treatment in an infusion center, at home or at a physician's office - providing more flexibility and freedom of choice that can make daily living easier for gMG patients and their caregivers," said Allison Foss, Executive Director of the Myasthenia Gravis Association.

Phase 3 ADAPT-SC Bridging Study

"The clinical trials of VYVGART continue to show significant benefit to patients with a favorable safety profile and clear improvements in gMG disease scores. Now with the approval of VYVGART Hytrulo, we have a broad gMG treatment offering with both IV and SC administration options and can select based on patient needs and preference without sacrificing clinical benefit or safety," said James F. Howard Jr., M.D., Professor of Neurology (Neuromuscular Disease), Medicine and Allied Health, Department of Neurology, The University of North Carolina at Chapel Hill School of Medicine and Principal Investigator for the ADAPT-SC trial.

This FDA approval is based on positive results from the Phase 3 ADAPT-SC study, which established the efficacy of VYVGART Hytrulo by demonstrating a reduction in anti-AChR antibody levels comparable to intravenous VYVGART in adult gMG patients. ADAPT-SC was a bridging study to the Phase 3 ADAPT study, which formed the basis for approval of intravenous VYVGART in December 2021.

In the ADAPT-SC study, the primary endpoint of noninferiority was met ($p < 0.0001$) and VYVGART Hytrulo demonstrated mean total IgG reduction of 66.4% from baseline at day 29, compared to 62.2% with VYVGART. Additional key secondary endpoints were met, which were consistent with efficacy measures from the ADAPT study identifying the correlation between total IgG reduction and clinical benefit in gMG.

VYVGART Hytrulo has a demonstrated safety profile, consistent with the ADAPT clinical trial with the exception of injection site reactions (ISRs), which were higher with VYVGART Hytrulo. It was generally well-tolerated with ISRs being the most frequent adverse events. All ISRs, which are commonly observed with biologics administered subcutaneously, were mild to moderate, and resolved over time.

Access to VYVGART Hytrulo

VYVGART Hytrulo is expected to be available for patients in the U.S. in July 2023. argenx is committed to supporting access for patients to its medicines and has decided to price VYVGART Hytrulo at parity to VYVGART on a net annual revenue basis.

Throughout their treatment journey, patients can access VYVGART Hytrulo in the same personalized way they access VYVGART today with support from My VYVGART Path. Program resources include disease and product education, access support and benefits verification, and financial assistance programs for eligible patients. Patients and clinicians can access more information at [VYVGARTHytrulo.com](https://www.vyvgart.com/hytrulo).

Marketing authorization applications for SC efgartigimod are under review by the European Medicines Agency with a decision expected by the end of 2023, and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) with a decision expected by the first quarter of 2024.

Conference Call Details

argenx will host a conference call tomorrow, June 21, 2023, at 2:30 pm CET (8:30am 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:

Please dial in 15 minutes prior to the live call.

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 9752
Switzerland	41 43 210 11 32

See 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 Phase 3 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 VYVGART Hytrulo compared with VYVGART in adult patients with gMG. The pharmacodynamic effect was measured by percent change from baseline in autoantibody (AChR) 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 VYVGART Hytrulo 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 VYVGART[®] Hytrulo

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.

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-and-only approved neonatal Fc receptor (FcRn) blocker in the U.S., Japan, Israel, the EU and the UK. 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 "believes," "hope," "estimates," "anticipates," "expects," "intends," "may," "will," or "should" and include statements argenx makes concerning the benefits and safety profile of VYVGART; the expected availability of VYVGART Hytrulo; and the timing and outcome of marketing authorizations for VYVGART Hytrulo by the European Medicines Agency and Japan's Pharmaceuticals and Medical Devices Agency. 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. 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 publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.