argenx Announces Positive Topline Results from Phase 3 ADAPT OCULUS Trial of VYVGART in Ocular Myasthenia Gravis

February 26, 2026

- *Study met primary endpoint (p-value = 0.012)*
- *First registrational study to specifically evaluate a targeted treatment for patients living with ocular MG*
- *Results support planned Supplemental Biologics License Application (sBLA) submission to U.S. Food and Drug Administration (FDA) to expand label into oMG*

Regulated Information – Inside Information

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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 positive topline results from the Phase 3 ADAPT OCULUS study evaluating VYVGART® (efgartigimod alfa and hyaluronidase-qvfc) in adults with ocular myasthenia gravis (oMG).

ADAPT OCULUS met its primary endpoint (p-value=0.012), showing that patients living with oMG and treated with VYVGART demonstrated statistically significant improvement from baseline in Myasthenia Impairment Index (MGII) Patient Reported Outcome (PRO) ocular scores at Week 4 compared to placebo. In the overall population, mean change from baseline in patients treated with VYVGART was a 4.04 point improvement in MGII PRO versus a mean change of 1.99 MGII PRO score in patients treated with placebo. Patients treated with VYVGART experienced a marked reduction of key ocular symptoms: diplopia (double vision) and ptosis (drooping of the upper eyelids).

“Ocular myasthenia gravis significantly impacts patients’ daily lives, affecting vision, independence and the ability to do routine tasks, such as work or drive a car. Yet today, there are no approved targeted medicines for this disease,” said Carolina Barnett-Tapia, M.D., Ph.D., Associate Professor of Medicine (Neurology) at the University of Toronto. “The improvements observed with VYVGART in the OCULUS trial offer hope to the thousands of myasthenia gravis patients with ocular involvement.”

VYVGART was well tolerated and had a favorable safety profile in patients with oMG, consistent with prior studies. No new safety concerns were identified.

“ADAPT OCULUS is the first registrational study specifically designed to evaluate a targeted therapy for ocular myasthenia gravis,” said Luc Truyen, M.D., Ph.D., Chief Medical Officer of argenx. “Ocular MG has been historically under-studied and represents a significant unmet need in the MG community. These positive results deliver on our patient-centered approach to drug development and bring us one step closer to our vision of delivering a targeted, transformative treatment option to as many MG patients as possible and ensuring no patient is left behind.”

Data from the ADAPT OCULUS study will be presented at an upcoming medical meeting.

About the ADAPT OCULUS Study Design

ADAPT OCULUS is a Phase 3, randomized, double-blind, placebo-controlled, parallel-group design study evaluating the efficacy and safety of VYVGART SC administered by prefilled syringe in adult patients with ocular MG (MGFA Class I) (n=141) across North America, Europe and Asia-Pacific. In Part A, randomized participants (1:1) received four once-weekly injections of efgartigimod PH20 SC or placebo PH20 SC followed by a 4-week follow-up. In Part B, open-label extension, participants received 2 cycles of four once-weekly efgartigimod injections with a 4-week interval between cycles. Additional cycles from Cycle 3 onward could start ≥1 week after the last administration of the previous cycle, based on clinical status.

The primary endpoint was the change from baseline in Myasthenia Gravis Impairment Index (MGII) (patient-reported outcome [PRO] subcomponent) ocular score at week 4 (day 29) compared to placebo in Part A. Enrolled participants were either seropositive or seronegative for AChR-Ab, and MGFA Class I with only ocular muscle weakness as determined by an MGII (PRO) ocular score of ≥6 with at least 2 ocular items with a score of ≥2. Participants were on a stable dose of gMG treatment prior to randomization, including acetylcholinesterase inhibitors, corticosteroids or nonsteroidal immunosuppressive drugs.

MGII is a validated measure of disease severity based on the signs and symptoms of myasthenia gravis and includes an ocular-specific subdomain that evaluates the two key clinical symptoms of oMG: diplopia and ptosis.

Important Safety Information

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.

Important Safety Information

What is VYVGART HYTRULO® (efgartigimod alfa and hyaluronidase-qvfc)?

VYVGART HYTRULO is a prescription medicine used to treat adults with:

- **generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.**
- **chronic inflammatory demyelinating polyneuropathy (CIDP).**

It is not known if VYVGART HYTRULO is safe and effective in children.

IMPORTANT SAFETY INFORMATION
Do not take VYVGART HYTRULO if you are allergic to efgartigimod alfa, hyaluronidase, or any of the ingredients in VYVGART HYTRULO. VYVGART HYTRULO can cause serious allergic reactions and a decrease in blood pressure leading to fainting.

Before taking VYVGART HYTRULO, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection or fever.
- have recently received or are scheduled to receive any vaccinations.
- have any history of allergic reactions.
- have kidney (renal) problems.
- are pregnant or plan to become pregnant. It is not known whether VYVGART HYTRULO will harm your unborn baby.
    - Pregnancy Exposure Registry. There is a pregnancy exposure registry for women who use VYVGART HYTRULO during pregnancy. The purpose of this registry is to collect information about your health and your baby. Your

healthcare provider can enroll you in this registry. You may also enroll yourself or get more information about the registry by calling 1-855-272-6524 or going to VYVGARTPregnancy.com
- are breastfeeding or plan to breastfeed. It is not known if VYVGART HYTRULO passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

VYVGART HYTRULO can cause side effects which can be serious, including:

- **Infection.** VYVGART HYTRULO may increase the risk of infection. If you have an active infection, your healthcare provider should delay your treatment with VYVGART HYTRULO until your infection is gone. Tell your healthcare provider right away if you get any of the following signs and symptoms of an infection: fever, chills, frequent and painful urination, cough, pain and blockage or nasal passages, wheezing, shortness, sore throat, excess phlegm, nasal discharge.
- **Allergic reactions (hypersensitivity reactions).** VYVGART HYTRULO can cause allergic reactions that can be severe. These reactions can happen during, shortly after, or weeks after your VYVGART HYTRULO injection. Tell your healthcare provider or get emergency help right away if you have any of the following symptoms of an allergic reaction: rash, swelling of the face, lips, throat, or tongue, shortness of breath, hives, trouble breathing, low blood pressure, fainting.
- **Infusion or injection-related reactions.** VYVGART HYTRULO can cause infusion or injection-related reactions. These reactions can happen during or shortly after your VYVGART HYTRULO injection. Tell your healthcare provider if you have any of the following symptoms of an infusion or injection-related reaction: high blood pressure, chills, shivering, chest, stomach, or back pain.

The most common side effects of VYVGART HYTRULO include respiratory tract infection, headache, urinary tract infection, and injection site reactions.

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 FDA at 1-800-FDA-1088.

Please see the full Prescribing Information for VYVGART HYTRULO and talk to your doctor.

About VYVGART and VYVGART Hytrulo

VYVGART® (efgartigimod alfa fcab) is a first-in-class human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG autoantibodies. VYVGART® Hytrulo is a subcutaneous combination of efgartigimod alfa (VYVGART) and recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE ® drug delivery technology to facilitate subcutaneous injection delivery of biologics. VYVGART is approved for generalized myasthenia gravis (gMG) and immune thrombocytopenia (Japan only). VYVGART Hytrulo is approved for gMG and chronic inflammatory demyelinating polyneuropathy (CIDP). VYVGART Hytrulo may be marketed under different proprietary names in other regions.

About Ocular Myasthenia Gravis (oMG)

Ocular myasthenia gravis (oMG) is a rare and chronic autoimmune disease characterized by muscle weakness limited to the muscles controlling the eyes and eyelids. Symptoms commonly include ptosis (drooping eyelids), diplopia (double vision), and fluctuating visual disturbance that can impair daily activities. Approximately 80% of myasthenia gravis (MG) patients initially present with ocular symptoms, and up to 92% experience ocular involvement at some point during the course of disease. While many progress to generalized myasthenia gravis (gMG), in 15–25% of patients, weakness remains restricted to the ocular muscles. oMG is driven by pathogenic IgG autoantibodies that disrupt communication at the neuromuscular junction. Despite the functional and quality-of-life burden associated with persistent ocular symptoms, there are currently no approved targeted therapies specifically for oMG. Treatment approaches often rely on symptomatic therapies and generalized immunosuppression, underscoring the need for additional therapeutic options for this distinct MG 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 and is evaluating its broad potential in multiple serious autoimmune diseases while advancing several earlier stage experimental medicines within its therapeutic franchises. For more information, visit www.argenx.com and follow us on LinkedIn, Instagram, Facebook, and YouTube.

This press release contains inside information within the meaning of Article 7(1) of the EU Market Abuse Regulation (Regulation 596/2014).

Media:
Colin McBean
cmcbean@argenx.com

Investors:

Alexandra Roy
aroy@argenx.com