argenx Announces VYVGART SC Prefilled Syringe for Self-Injection in Chronic Inflammatory Demyelinating Polyneuropathy Authorized for Sale by Health Canada

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argenx Canada Inc. →
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- *VYVGART® SC is first and only neonatal Fc receptor blocker approved to treat CIDP*
- *Authorization is based on global ADHERE study, the largest clinical trial in CIDP to date*
- *First novel, targeted therapy for CIDP treatment in 30 years*

TORONTO, Nov. 5, 2025 /CNW/ - argenx SE (EURONEXT: ARGX) (Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced that Health Canada has issued a Notice of Compliance authorizing VYVGART SC (efgartigimod alfa injection) as a monotherapy for the treatment of adult patients with active chronic inflammatory demyelinating polyneuropathy (CIDP).

VYVGART SC is authorized for CIDP as a once weekly 20-30 second subcutaneous injection in a prefilled syringe, offering patients the flexibility to self-administer or receive treatment from a caregiver or healthcare professional--at home, while 'on the go,' or in a clinical setting. With this milestone, VYVGART

SC becomes the first innovative treatment for CIDP in more than 30 years, and the first-and-only neonatal Fc receptor (FcRn) blocker authorized in Canada for CIDP.

"Many Canadian CIDP patients face progressive weakness, numbness and disability, and have had limited treatment options for far too long," said Hans Katzberg , M.D., Neuromuscular Neurologist and Division Head of Neurology, University Health Network Toronto. "The authorization of VYVGART SC marks a significant advance, potentially offering an important new way to effectively treat this challenging disease and improve outcomes while reducing the burden on patients."

CIDP is a rare, debilitating and often progressive autoimmune disorder of the peripheral nervous system. People living with CIDP experience a range of disabling mobility and sensory issues, such as difficulty standing from a seated position, pain, fatigue, and frequent tripping or falling. As the disease progresses, patients may require the use of a wheelchair and may be unable to work or participate in daily activities. Globally, 85% of patients require ongoing treatment and nearly 88% of treated patients continue to experience residual impairment and disability.

Currently available CIDP treatments include intravenous immunoglobulin (IVIg) and subcutaneous immunoglobulin (SCIg) with CIDP patients accounting for approximately 20% of IVIg/SCIg use in Canada[1]. Demand for human-derived blood products continues to grow at 7-8% annually in Canada[2], underscoring the importance of new, targeted treatment alternatives such as VYVGART SC to help reduce demand and support future supply of blood products.

The Health Canada authorization is supported by positive results from the ADHERE study, the largest clinical trial conducted to date in CIDP. In this study, 69% (221/322) of patients treated with VYVGART SC, regardless of prior treatment, demonstrated evidence of clinical improvement, including enhanced mobility, function, and strength. The study met its primary endpoint ($p<0.0001$), showing a 61% reduction (HR: 0.39, 95% CI: 0.25; 0.61) in the risk of relapse versus placebo. The safety results were generally consistent with the known safety profile of VYVGART in previous clinical studies and real-world use. Nearly all (99%) participants chose to participate in the ADHERE+ open-label extension study.

"Health Canada's authorization of VYVGART SC for CIDP is an encouraging and important step forward for Canadians living with this rare condition," said Stacey Lintern, Chief Executive Officer, Muscular Dystrophy Canada. "Insights from our Canadian CIDP Patient Journey Mapping initiative show the value of flexible treatment options that promote independence, continuity of care, and day-to-day stability. The availability

of a subcutaneous option represents meaningful progress in improving both access and patient experience. We look forward to seeing this therapy made available to Canadians who may benefit from it, as authorization is only the first step toward equitable access."

"Patients living with CIDP have varying disabilities that can profoundly affect their social lives and careers," said Donna Hartlen, Executive Director, GBS/CIDP Foundation of Canada. "This authorization of VYVGART SC by Health Canada is the first step toward offering more treatment options and fair access for individuals living with CIDP."

According to feedback from patients and clinicians provided to the Canadian Drug Agency (CDA) and the National Institute for Excellence in Health and Social Services (INESSS), 30-40% of patients may not be adequately treated with conventional therapies[3].

"Patients have been waiting a long time, and today, argenx is proud to deliver the first innovative treatment modality for CIDP in more than 30 years," said John Haslam, General Manager, argenx Canada. "Building on our commitment to generalized Myasthenia Gravis patients, VYVGART's first indication, we are committed to partnering with stakeholders across Canada to provide a new treatment option for CIDP patients and potentially reduce the demand for human-derived blood products."

About ADHERE

The ADHERE trial was a multi-center, randomized, double-blind, placebo-controlled trial evaluating efgartigimod alfa SC for the treatment of CIDP. ADHERE enrolled 322 adult patients with CIDP. The trial consisted of an open-label Stage A followed by a randomized, placebo-controlled Stage B. In order to be eligible for the trial, the diagnosis of CIDP was confirmed by an independent panel of experts. Patients entered a run-in stage, where any ongoing CIDP treatment was stopped and, in order to be eligible for Stage A, had to demonstrate active disease with clinically meaningful worsening on at least one CIDP clinical assessment tool, including INCAT, I-RODS, or mean grip strength. Treatment-naïve patients were able to skip the run-in period with proof of recent worsening. To advance to Stage B, patients needed to demonstrate evidence of clinical improvement (ECI) with efgartigimod alfa SC. ECI was achieved through improvement of the INCAT score, or improvement on I-RODS or mean grip strength if those scales had demonstrated worsening during the run-in period. In Stage B, patients were randomized to either efgartigimod alfa SC or placebo for up to 48 weeks. The primary endpoint was measured once 88 total

relapses or events were achieved in Stage B and was based on the hazard ratio for the time to first adjusted INCAT deterioration (i.e., relapse). After Stage B, all patients had the option to roll-over to an open-label extension study to receive efgartigimod alfa SC.

About Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

CIDP is a rare and serious autoimmune disease of the peripheral nervous system. 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 worsen 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 SC

VYVGART SC 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 SC injection delivery of biologics. In binding to the neonatal Fc receptor (FcRn), VYVGART results in the reduction of circulating IgG autoantibodies. It is marketed as VYVGART® Hytrulo in the U.S., VYVGART® in Europe, VYVDURA® in Japan, and may be marketed under different proprietary names following approval in other regions.

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**.

References

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