argenx Announces FDA Approval of VYVGART Hytrulo Prefilled Syringe for Self-Injection in Generalized Myasthenia Gravis and Chronic Inflammatory Demyelinating Polyneuropathy

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- *VYVGART, the first-in-class FcRn blocker, now offers three administration options, including self-injection with a prefilled syringe*
- *Self-injection provides gMG and CIDP patients with flexibility for when and where to receive treatment – at home, while 'on the go' or in a healthcare setting*
- *Approval reflects commitment to innovating the patient experience with individualized, safe and effective therapies*

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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 that the U.S. Food and Drug Administration (FDA) approved a new option for patients to self-inject VYVGART® Hytrulo with a prefilled syringe (efgartigimod alfa and hyaluronidase-qvfc) for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive and adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

"Today's FDA approval provides a new self-injection option across both approved indications in the U.S. that is designed for patients who seek more independence with their treatment," said Luc Truyen M.D., Ph.D., Chief Medical Officer, argenx. "We understand patients experience MG and CIDP in different ways, and our prefilled syringe is an important innovation that provides patients with more freedom and flexibility to self-administer VYVGART Hytrulo. Whether patients prefer to receive their treatment in a physician's office, at home, or while traveling, they can experience treatment on their own terms and continue to benefit from VYVGART Hytrulo's favorable safety profile and strong efficacy."

VYVGART Hytrulo prefilled syringe for self-injection is approved as a 20-to-30-second subcutaneous injection administered by a patient, caregiver, or healthcare professional. Patients are able to self-inject after proper instruction in subcutaneous injection technique. The single dose prefilled subcutaneous injection was developed as part of argenx's exclusive partnership with Halozyme's ENHANZE® drug delivery technology, which enables rapid, high-volume delivery of biologics.

"I am excited to offer my patients living with gMG and CIDP the option of the new prefilled syringe for VYVGART Hytrulo," said Dr. Beth Stein, M.D., Director of Neuromuscular Diseases, St. Joseph's Health, Clifton, NJ. "This new self-injection option will lead to more convenient and flexible administration for patients, empowering them to decide when and where they receive treatment. A ready-to-use option enhances patient independence and reduces the time required for treatment, making disease management and control more seamless."

The approval of VYVGART Hytrulo prefilled syringe for self-injection is supported by data from studies evaluating its bioequivalence to VYVGART Hytrulo in a vial. In addition, human factors validation studies demonstrated that participants with gMG or CIDP, or their caregivers, safely and successfully prepared

and administered VYVGART Hytrulo with the prefilled syringe. Previous FDA approval of VYVGART Hytrulo for patients with gMG and CIDP was based on the global Phase 3 ADAPT, ADAPT-SC and ADHERE trials.

"argenx is a trusted partner in the MG patient community, continuously innovating to meet the evolving needs of patients. This new self-injection option is a natural progression, empowering individuals to take control of their treatment and working toward achieving a greater sense of normalcy in their lives," said Samantha Masterson, President and CEO of the Myasthenia Gravis Foundation of America.

"The daily burden of CIDP from both the symptoms of the disease and interruption to daily life creates profound unseen challenges for patients," said Lisa Butler, Executive Director, GBS-CIDP Foundation. "Effective new treatments that reduce the need for frequent clinic visits are a welcome option for active patients seeking to regain time and a sense of normalcy in their daily routine. Today's news about the approval of argenx's prefilled syringe for at-home self-injection is a significant step forward for those patients seeking a new treatment option."

Access Support for VYVGART Hytrulo Prefilled Syringe

The argenx patient support program, My VYVGART® Path, can help patients and healthcare providers navigate access. My VYVGART Path resources include disease and product education, access support and benefits verification, and financial assistance programs for eligible patients. argenx is committed to supporting access for patients to its medicines, including VYVGART Hytrulo prefilled syringe.

More information is available at VYVGART.com.

See FDA-approved 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 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:

- 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 accompanying full Prescribing and Patient Information for VYVGART HYTRULO.

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 Generalized Myasthenia Gravis (gMG)

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[1], where muscles throughout the body may be affected. Patients with confirmed AChR antibodies account for approximately 85% of the total gMG population.

About Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Chronic inflammatory demyelinating polyneuropathy (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 get worse 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 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, X/Twitter, Instagram, Facebook, and YouTube.

References

1 Behin et al. New Pathways and Therapeutics Targets in Autoimmune Myasthenia Gravis. J Neuromusc Dis 5. 2018. 265-277

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

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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 “aim,” “are,” “can,” “continue,” “may,” and “will” and include statements argenx makes concerning the potential impact of the VYVGART Hytrulo prefilled syringe for self-injection for gMG and CIDP patients, including the increased convenience and flexibility of administration and the benefit of VYVGART Hytrulo’s safety profile and efficacy; Halozyme’s ENHANZE® drug delivery technology’s ability to develop rapid, high-volume delivery of biologics; its commitment to innovating the patient experience with individualized, safe and effective therapies; its commitment to supporting access for patients to its medicines, including the VYVGART Hytrulo prefilled syringe; 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 the development of novel drug therapies; preclinical and clinical trial and product development activities and regulatory approval requirements; the acceptance of its products and product candidates by its patients as safe, effective and cost-effective; the impact of governmental laws and regulations, including tariffs, export controls, sanctions and other regulations on its business; its reliance on third-party suppliers, service providers and manufacturers; inflation and deflation and the corresponding fluctuations in interest rates; and regional instability and conflicts. 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.