**November 7, 2026, 10:00 AM ET**

**Amsterdam, the Netherlands** – argenx SE (Euronext & Nasdaq: ARGX), the immunology innovation company, today announced that data from the Phase 3 ALKIVIA study demonstrating rapid and sustained improvement with VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) in patients with autoimmune myositis will be featured in a late-breaking oral presentation (#LB24) at the American College of Rheumatology (ACR) Convergence 2026 on November 11, 2026, from 9:15-9:30 a.m. ET.

**Combined IMNM and DM population: Primary and key secondary endpoints met**
The study met its primary endpoint in the combined immune-mediated necrotizing myopathy (IMNM) and dermatomyositis (DM) patient population, demonstrating that patients treated with efgartigimod achieved a statistically significant and clinically meaningful 15.4-point greater improvement in mean Total Improvement Score (TIS) at Week 52 versus placebo (p=0.0011; 48.0 vs 32.6). The study also met key secondary endpoints in the combined population, including response rate, time to response, muscle strength, and disease activity.

Efgartigimod was generally well tolerated by patients. The observed safety profile was consistent with prior studies and the known safety profile of efgartigimod.

“These Phase 3 results add to the growing body of evidence that targeting FcRn delivers a meaningful, sustained benefit for people with autoimmune myositis,” said Luc Truyen, M.D., Ph.D., Chief Medical Officer, argenx. “ALKIVIA demonstrates the clinical relevance of reducing pathogenic autoantibodies, strengthening the case for efgartigimod to be the first targeted treatment for IMNM. We are moving with urgency to bring efgartigimod to people living with IMNM, who have no approved treatments, and we remain committed to advancing efgartigimod for people living with DM.”

**IMNM: Rapid, sustained improvement supports potential first approved treatment**
IMNM patients treated with efgartigimod demonstrated a clinically meaningful 14.8-point greater improvement in mean TIS versus placebo at Week 52 (p=0.0048; 45.1 vs 30.2).

- **Early, durable response:** A greater proportion of patients treated with efgartigimod achieved a mean TIS of 40 or more (TIS ≥ 40) at Week 52 versus those on placebo (22.0 percentage-point difference) and were twice as likely to maintain that response through Week 52.
- **Greater muscle strength:** Patients treated with efgartigimod experienced greater improvement (5.4 points) versus placebo in Manual Muscle Testing-8 (MMT-8), which evaluates strength across eight muscle groups.
- **Reduced muscle injury:** Creatine kinase (CK) levels decreased rapidly in patients treated with efgartigimod and remained lower through Week 52, with a

43.5 percentage-point greater reduction from baseline versus placebo, as well as greater improvement in CK grade (0.9-grade greater reduction). CK is a key biomarker of active muscle injury.

- **Improvements in disease activity:** Patients and physicians both reported greater improvement in disease activity with efgartigimod versus placebo at Week 52 as measured by the Patient Global Assessment of Disease Activity (PGA) and Physician Global Assessment of Disease Activity (MDGA).

Based on the ALKIVIA results, argenx plans to submit a Supplemental Biologics License Application (sBLA) with the U.S. Food and Drug Administration (FDA) for efgartigimod in IMNM by the end of 2026, supported by a Breakthrough Therapy Designation from the FDA.

**DM: Clinically meaningful treatment effect supports targeting FcRn**
In the DM patient population, a clinically meaningful 14.5-point greater improvement versus placebo in mean TIS at Week 52 was observed (p=0.1093; 51.5 vs 37.0), though statistical significance was not reached in this smaller cohort.

- **Early, sustained response:** A greater proportion of patients treated with efgartigimod achieved TIS ≥ 40 versus placebo (27.2 percentage-point difference). Separation from placebo patients was evident from Week 4 and maintained through Week 52.
- **Improved skin disease:** Patients treated with efgartigimod showed a clear improvement in skin disease severity (5.6-point greater improvement at Week 52) versus placebo, as measured by the Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI), with improvement seen from Week 4.
- **Improved disease activity:** Patients and physicians both reported greater improvement in disease activity with efgartigimod versus placebo at Week 52, as measured by the PGA and MDGA.

More information on the data presented at the ACR Convergence 2026 Annual Meeting can be found here.

**About the ALKIVIA Study**
The ALKIVIA study was a global, randomized, double-blind, placebo-controlled, multicenter, operationally seamless Phase 2/3 study of efgartigimod SC for the treatment of autoimmune myositis across immune-mediated necrotizing myopathy (IMNM), dermatomyositis (DM) and polymyositis (PM). The ALKIVIA study randomized 265 patients who had active disease and were on background treatment. Participants were randomized (1:1) to receive weekly injections of efgartigimod PH20 SC or matched placebo PH20 SC. The study was conducted in two phases, with an analysis of the Phase 2 portion of the clinical trial after the first 89 patients completed the study,

followed by Phase 3. In the Phase 3 study, 175 patients received treatment. The Phase 3 study included a protocol-mandated corticosteroid taper throughout the study. The primary endpoint of Phase 3 was the mean Total Improvement Score (TIS) at the end of the treatment period of 52 weeks of all treated patients compared to placebo. Prespecified analyses evaluated the combined IMNM and DM population and each subtype separately.

ALKIVIA was conducted globally across North and South America, Europe, and Asia-Pacific, including China and Japan. argenx has an exclusive license agreement with Zai Lab for the development and commercialization of VYVGART and VYVGART Hytrulo in Greater China. Through this agreement, Zai Lab recruited Chinese patients into the ALKIVIA trial.

**About Autoimmune Myositis**
Autoimmune myositis is a heterogenous disease spectrum with autoimmune-mediated pathophysiology, characterized by chronic inflammation and progressive muscle weakness, and in some subtypes by skin involvement and other extramuscular manifestations. Proximal muscle weakness is a hallmark clinical feature across subtypes.

Approximately 100,000 people in the United States live with autoimmune myositis, including approximately 20,000 with immune-mediated necrotizing myopathy (IMNM) and approximately 40,000 with dermatomyositis (DM). Up to 80% of patients report long-term disability despite treatment. There are currently no selectively targeted treatments available, and care and treatment relies primarily on corticosteroids and broad immunosuppressants, which are associated with significant cumulative toxicity, including metabolic, cardiovascular, musculoskeletal and infectious complications.

Advances in the understanding of autoimmune myositis biology have highlighted the central role of antibody-mediated immunity, with pathogenic IgG autoantibodies contributing to muscle fiber damage and extramuscular manifestations across subtypes. FcRn maintains circulating IgG levels by recycling IgG antibodies, including pathogenic autoantibodies.

**About Immune-mediated Necrotizing Myopathy**
Immune-mediated necrotizing myopathy (IMNM) is a subtype of autoimmune myositis and is characterized as a sudden and severe loss of muscle strength, progressing to difficulty walking, lifting arms, or maintaining independent mobility. The rapid onset and aggressive nature of the disease can often lead to hospitalization, intensive treatment, and reliance on caregivers, which can make the patient experience acute and destabilizing. As the disease progresses, healthy muscle tissue is permanently replaced by fat and scar tissue. Approximately 20,000 IMNM patients are diagnosed in the U.S.

**About Dermatomyositis**
Dermatomyositis (DM) is a subtype of autoimmune myositis and is characterized as muscle weakness and distinctive skin rashes that can be painful, itchy, or highly visible on the face, chest, and hands. DM can also be associated with rapidly progressive interstitial lung disease and is strongly associated with malignancy. Some patients have reported increased self-consciousness, stigma, and social withdrawal, making the emotional burden more pronounced. Approximately 40,000 DM patients are diagnosed in the U.S.

**About Efgartigimod and Efgartigimod SC**
Efgartigimod (efgartigimod alfa fcab) is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG autoantibodies. It is the first approved FcRn blocker for the treatment of generalized myasthenia gravis (gMG) and chronic inflammatory demyelinating polyneuropathy (CIDP) globally, and for primary immune thrombocytopenia (ITP) in Japan. Efgartigimod SC is a subcutaneous combination of efgartigimod alfa and recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology to facilitate subcutaneous injection delivery of biologics.

**What is VYVGART HYTRULO® (efgartigimod alfa and hyaluronidase-qvfc)?**
VYVGART HYTRULO is a prescription medicine used to treat adults with:

- generalized myasthenia gravis (gMG)
- 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 of nasal passages
  - wheezing
  - shortness of breath

- **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

- **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

**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 and full Prescribing Information for VYVGART HYTRULO.

**About argenx**
argenx is the immunology innovation company, focused on turning immunology breakthroughs into medicines for patients. The company seeks novel biology wherever it emerges, co-creating with academic researchers through its Immunology Innovation Program (IIP) and investing in promising science, to develop treatments for people living with underserved diseases. By advancing molecules with the potential to reach multiple diseases and patient populations, argenx is building a world-class portfolio. This approach produced the first approved antibody fragment targeting the neonatal Fc receptor (FcRn) and today powers a growing pipeline of early and late-stage programs across several therapeutic areas. For more information, visit www.argenx.com and follow us on LinkedIn, Instagram, Facebook, and YouTube.

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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 generally can be identified by the use of forward-looking words, such as “aim”, “anticipate”, “aspire”, “believe”, “can”, “continue”, “could”, “estimate”, “expect”, “entail”, “forecast”, “future”, “goals”, “hope”, “intend”, “is designed to”, “likely”, “may”, “might”, “objective”, “plan”, “possible”, “potential”, “pursue”, “project”, “predict”, “seek”, “should”, “strategy”, “target”, “will” and other words and terms of similar meaning and expression, including

in connection with any discussion of future operating or financial performance. 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; uncertainties associated with the development of novel drug therapies; preclinical and clinical trial and product development risks and setbacks; interpretation of argenx's clinical trial data by regulatory authorities and argenx's ability to obtain regulatory approval; the risk that early stage clinical trials may not be predictive of results in later stage or large scale clinical trials; the occurrence of adverse safety events or participant dropouts; 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; the impact of healthcare regulations, including rules on reimbursement for argenx's products; competition in drug discovery, development and commercialization efforts; its reliance on third-party suppliers, service providers and manufacturers; and instability and conflicts in the regions in which the company has suppliers or markets for its products. A further list and description of these and other risks, uncertainties, and factors that could cause actual results to differ materially from those referred to in the forward-looking statements 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 risks and uncertainties, the reader is advised not to place undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this press release. 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.