

argenx to Present Phase 3 ALKIVIA Results in Autoimmune Myositis as a Late-Breaking Oral Presentation at ACR Convergence 2026

- *Results from the global Phase 3 ALKIVIA study, the first registrational study investigating an FcRn blocker in autoimmune myositis, show efgartigimod provides clinically meaningful improvements in IMNM and DM*
- *Patient improvements observed as early as Week 4 and sustained through 52 weeks*
- *Late-breaking oral presentation on Wednesday, November 11th, 9:15 – 9:30 AM ET*

October 19, 2026, 8:00 AM ET

Amsterdam, the Netherlands – argenx SE (Euronext & Nasdaq: ARGX), the immunology innovation company, today announced that new data from the Phase 3 study evaluating VYVGART® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) in patients with autoimmune myositis, focused on immune-mediated necrotizing myopathy (IMNM) and dermatomyositis (DM), will be featured as a late-breaking oral presentation (#LB24) during the American College of Rheumatology (ACR) Convergence 2026 from November 6-11, 2026, in Orlando, Florida.

“ALKIVIA provides the first Phase 3 evidence that precisely targeting FcRn with efgartigimod can deliver clinically meaningful benefit for patients living with autoimmune myositis, for which very few treatment options exist, and in the case of IMNM, patients have no approved treatment options at all,” said Luc Truyen, M.D., Ph.D., Chief Medical Officer, argenx. “At ACR, we look forward to sharing ALKIVIA results that deepen the rheumatology community’s understanding of how IgG autoantibodies drive IMNM and DM and advance our ambition to transform the treatment paradigm.”

In the ALKIVIA study, efgartigimod showed rapid, sustained, and clinically meaningful improvements

- The Phase 3 ALKIVIA study met its primary endpoint, achieving a 15.4-point greater improvement in mean Total Improvement Score (TIS) versus placebo at Week 52 in the combined IMNM and DM population (47.95 vs. 32.56; p=0.0011).
- Improvements in disease activity for the combined IMNM and DM population were observed as early as Week 4 and were sustained through the full 52 weeks of treatment, even with steroid tapering.
- A greater proportion of IMNM as well as DM patients achieved a mean total improvement score of 40 or more (TIS ≥ 40) when treated with efgartigimod versus placebo. The median time to reach TIS ≥ 40 was also shorter with efgartigimod for both subtypes and was sustained through the full 52 weeks of treatment.

- Efgartigimod was well-tolerated in the study. The observed safety profile of efgartigimod was consistent with prior studies and the known safety profile of efgartigimod.

Details for the oral presentation are as follows:

- **Efgartigimod PH20 SC in Adults With Idiopathic Inflammatory Myopathy: Results From the Phase 3, Randomized, Placebo-Controlled ALKIVIA Trial, LB24**

Lead Author: Dr. Rohit Aggarwal

Date: Wednesday, November 11, 9:15 – 9:30 a.m. ET

More information on the data presented at the ACR Convergence 2026 Annual Meeting can be found [here](#).

About the ALKIVIA study

The ALKIVIA trial 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 IMNM, DM and 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 176 patients in 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. Scored from 0-100, TIS is an ACR/EULAR-validated composite endpoint based on six core set measures, including assessment of muscle strength and function; higher TIS values reflect greater overall clinical improvement. A TIS ≥ 40 is regarded by the clinical community as the point at which noticeable improvements in muscle strength, injury and functionality are observed.

ALKIVIA was conducted globally across North 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 heterogeneous 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 targeted, selective 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.

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.

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.