argenx Presents New Efgartigimod Data Showing Long-Term Sustained Patient Benefit in Myositis and Sjogren's Disease at EULAR 2026

June 3, 2026

- *ALKIVIA+ data in myositis indicate efgartigimod provides sustained, clinically meaningful improvements and consistent safety*
- *RHO+ data in Sjogren's disease indicate maintenance of response following switch to biweekly dosing*
- *Cross-indication analysis of efgartigimod data across rheumatology studies underscores consistent safety profile in large patient population*

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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 the presentation of new data evaluating VYVGART® (IV: efgartigimod alfa-fcab and SC or Hytrulo: efgartigimod alfa and hyaluronidase-qvfc) across autoimmune rheumatic diseases, including myositis and Sjogren's disease, to be presented at the European Alliance of Associations for Rheumatology (EULAR) 2026 Congress from June 3-6, 2026, in London, UK.

"Our presentations at EULAR further support the rationale for targeting FcRn in autoimmune rheumatic diseases and underscore its potential to address significant unmet patient need," said Luc Truyen, M.D., Ph.D., Chief Medical Officer at argenx. "We are encouraged by the consistency of the long-term data as well as data underscoring efgartigimod's favorable safety profile across multiple autoimmune rheumatic diseases. We are looking forward to additional results evaluating efgartigimod in myositis later this year as well as in Sjogren's disease next year."

Myositis and Sjogren's disease are both chronic, progressive autoimmune diseases that are generally more common in women than men. Myositis can cause serious and irreversible damage to muscles and organs, leading to a loss of independence and a significant burden for patients. Sjogren's disease can cause dry eyes and mouth, chronic fatigue, and joint pain. It can also affect multiple organ systems and lead to nervous system complications.

Efgartigimod provides sustained functional improvement in patients with myositis

ALKIVIA+ is an ongoing open-label extension study that enrolled patients who completed the 24-week, double-blind, placebo-controlled Phase 2 ALKIVIA trial, including those who continued efgartigimod treatment and those who transitioned from placebo to efgartigimod. Results presented at EULAR are an interim analysis through Week 52.

A key metric in ALKIVIA+ is Total Improvement Score (TIS). TIS is a composite index based on six core set measures, including muscle strength, physician and patient global assessments of disease activity, physical function, enzyme levels, and extramuscular activity. Higher TIS values reflect greater overall clinical improvement. Moderate and major improvement are defined as TIS ≥40 and ≥60, respectively.

Results showed:

- At 52 weeks, 37.5% of patients who had continuously received efgartigimod maintained their major TIS improvement from week 24. 33.3% of patients switching from placebo to efgartigimod achieved a similar major TIS improvement. Rates of moderate TIS improvement were also similar between the groups, at 75.0% and 66.7%, respectively.
- Sustained mean TIS benefit: Patients receiving continuous efgartigimod maintained clinically meaningful improvement through 52 weeks, with a mean TIS of 52.19. Patients who switched from placebo to efgartigimod achieved comparable improvement, with a mean TIS of 49.62 at week 52.
- The safety profile was consistent over the course of the study, with no increase in adverse events with longer exposure.
- These results further support the mechanistic relevance of FcRn blockade in myositis, providing further evidence that pathogenic autoantibodies are the underlying driver of disease.

"Patients with autoimmune myositis face the serious challenge that their immune system attacks their own body, causing irreversible muscle loss, weakness, pain and reduced quality of life, while the limited available treatments can carry significant side effects and be difficult to tolerate long term," said Hector Chinoy, M.D., Ph.D., presenting study author and Professor of Rheumatology and Neuromuscular Disease at The University of Manchester. "Emerging results from the ALKIVIA+ study suggest that efgartigimod has the potential to deliver meaningful and sustained clinical benefit for patients with myositis, with a favorable tolerability profile."

Topline results from the Phase 3 ALKIVIA study are expected in the third quarter of 2026.

Efgartigimod achieved maintenance of response in Sjogren's disease

RHO+, a 48-week open-label extension study, evaluated patients with Sjogren's disease who continued to receive efgartigimod, and those who

transitioned from placebo to efgartigimod after completing the 24-week double-blind treatment period of the Phase 2 RHO study.

Response to efgartigimod was assessed using the Composite of Relevant Endpoints for Sjogren's Syndrome (CRESS), a composite endpoint designed to capture overall treatment benefit across multiple clinical domains, including disease activity as measured by ClinESSDAI. Patients in the efgartigimod arm were switched to biweekly dosing based on ClinESSDAI response.

Results showed:

- Patients in the efgartigimod arm switching to biweekly dosing experienced maintenance of response on clinical measures.
- Patients in the placebo arm switching to efgartigimod experienced improvements in ClinESSDAI and increased CRESS response.
- At week 72, median ClinESSDAI scores were low in both groups: 2.5 in the efgartigimod arm and 2.0 in patients who transitioned from placebo to efgartigimod. Low disease activity is indicated by a ClinESSDAI score of <5.
- Efgartigimod was well tolerated, with no new safety signals identified following long-term use in participants with Sjogren's disease.

The Phase 3 UNITY trial is currently ongoing to assess efficacy and safety of efgartigimod in patients with moderate to severe Sjogren's disease. Topline results are expected in the second half of 2027.

Efgartigimod safety profile reinforced across autoantibody-driven autoimmune diseases

A cross-indication safety analysis of efgartigimod spanning multiple global clinical studies, including autoimmune rheumatic diseases, indicated that efgartigimod is consistently well-tolerated across diseases and administration methods.

- Data showed a consistent safety profile across 834 treated patients and more than 1,300 patient-years of follow-up. Efgartigimod was well tolerated in participants with autoimmune rheumatic diseases (myositis, Sjogren's disease, and lupus nephritis), consistent with findings from prior studies in other IgG-mediated autoimmune diseases and also consistent with what has been observed in approved indications globally.
- Adverse events were predominantly mild-to-moderate, and no increased event rates were seen in studies with a longer treatment duration.

Deepening understanding of the underlying biology

Additional argenx activities include: the presentation of the Phase 2 eSScape study design, evaluating the potential of efgartigimod in Systemic Sclerosis (SSc); an FcRn symposium exploring the role of autoantibodies in autoimmune rheumatic diseases and highlighting the potential of targeting FcRn; and the launch of a new myositis disease education campaign.

argenx additional information on the data at EULAR 2026 can be found here. Details for argenx presentations are as follows:

Title	Lead Author	Presentation
Myositis		
The Long-Term Safety and Efficacy of Efgartigimod PH20 SC in Adult Participants With Active Idiopathic Inflammatory Myopathy: Results From the Phase 2 Randomized ALKIVIA and Open-Label Extension ALKIVIA+ Trials	Rohit Aggarwal	Poster #POS0261 Friday, June 5 13:36 BST
Sjogren's Disease		
Long-Term Efficacy and Safety of Efgartigimod in Sjogren's Disease: Findings from the RHO+ Open-Label Extension Study	Isabelle Peene	Oral Presentation #130 Wednesday, June 3 17:30-17:40 BST
Systemic Sclerosis		
Efgartigimod PH20 Subcutaneous in Adults With Systemic Sclerosis: Design of a Phase 2, Randomized, Double-Blinded, Placebo-Controlled, Parallel-Group Study (eSScape)	Dinesh Khanna	Poster #POS0326 Friday, June 5 16:30 BST
Multiple Disease Areas		
Safety Profile of Efgartigimod Across Multiple Global Clinical Trials in Immunoglobulin G-Mediated Autoimmune Diseases With Emerging Data in Idiopathic Inflammatory Myopathy, Sjogren's Disease, and Lupus Nephritis	Hector Chinoy	Poster #POS1200 Saturday, June 6 10:15 BST

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 Myositis

Myositis is an autoimmune rheumatic disease that can be progressive and may lead to significant muscle and organ involvement, resulting in functional impairment and substantial burden for patients. It is characterized by skeletal muscle weakness with possible extramuscular manifestations involving the skin, joints, lungs, gastrointestinal tract, and heart. Major subtypes include immune-mediated necrotizing myopathy (IMNM), dermatomyositis (DM), polymyositis (PM), antisynthetase (ASyS), and inclusion body myositis, with muscle involvement being a common manifestation across most subtypes.

About ALKIVIA and ALKIVIA+ Study Design

The ALKIVIA study is a 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 enrolled 240 patients in total and is being conducted in two phases, with an analysis of the Phase 2 portion of the clinical trial after the first 90 patients completed the study, followed by a Phase 3 portion if a signal is observed in the Phase 2 portion. The primary endpoint is the mean total improvement score (TIS) at the end of the treatment period (24 weeks in Phase 2 and 52 weeks in Phase 3) of all treated patients (IMNM, DM and PM) compared to placebo. Key secondary endpoints include response rates at the end of treatment, time to response, and duration of response in TIS, as well as change from baseline in individual TIS components. Other secondary endpoints include quality of life and other functional scores. ALKIVIA+ is a 28-week open-label extension study that evaluated myositis patients who received continuous efgartigimod treatment and those who transitioned from placebo to efgartigimod after completing the 24-week double-blind, placebo-controlled Phase 2 ALKIVIA study. The primary endpoint of ALKIVIA+ is long-term safety and tolerability.

About Sjogren's Disease

Sjogren's disease is a chronic and progressive, systemic, autoimmune rheumatic disease associated with elevated autoantibodies and characterized by immune-mediated dysfunction of exocrine glands and extraglandular organ manifestations. Sjogren's disease can be severely debilitating and have a negative impact on patient quality of life, with common symptoms reported as dry eyes and mouth, fatigue, and joint pain. Sjogren's disease predominantly impacts women with a 9:1 female:male incidence ratio. Given the heterogeneous nature of the disease, the treatment journey can be challenging with long delays and high rates of misdiagnosis. There are no FDA-approved treatments targeting the disease itself, leaving current treatments to focus primarily on individual symptom management.

About RHO and RHO+ Study Design

The Phase 2 RHO study was a randomized, double-blinded, placebo-controlled multicenter proof-of-concept study to evaluate the safety and efficacy of efgartigimod in adults with Sjogren's disease. In order to enter the study, patients needed to test positive for anti-Ro autoantibodies and maintain residual salivary flow. Thirty-four patients were randomized 2:1 to receive either efgartigimod or placebo for up to 24 weeks. Multiple endpoints and biomarkers were evaluated in the signal-finding study, including the primary endpoint of CRESS (Composite of Relevant Endpoints for Sjogren's Syndrome). Within CRESS there are five components, spanning: systemic disease activity as measured by the ESSDAI (EULAR Sjogren's Syndrome Activity Index), patient reported outcomes as measured by the ESSPRI (EULAR Sjogren's Syndrome Patient Reported Index), tear and salivary gland function, and serology. To be a CRESS responder, patients needed to demonstrate a clinically meaningful benefit in at least 3 of the 5 composite items. Additional datapoints were gathered including the ClinESSDAI, STAR (Sjogren's Tool for Assessing Response), biomarker data, and the change in lymphocytic infiltrate levels through parotid biopsies.

RHO+ was a 48-week open-label extension study that evaluated the safety of efgartigimod in adult patients with Sjogren's disease who continued to receive efgartigimod IV, and those who transitioned from placebo to efgartigimod IV after completing the 24-week double-blind treatment period of the Phase 2 RHO study. The primary endpoint of RHO+ was incidence and severity of AEs and AESIs, incidence of SAEs, changes in laboratory test results, vital signs, and ECG results.

About UNITY Study Design

UNITY is an ongoing Phase 3 randomized, double-blinded, placebo-controlled multicenter study with open-label extension to evaluate the efficacy, safety, and tolerability of subcutaneously administered efgartigimod PH20, in adult participants with moderate-to-severe primary Sjogren's disease.

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.

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Forward-looking Statements

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