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PRESS RELEASE

Novartis ianalumab two-year data at ACR show further improvements in Sjögren's disease activity

- *Patients continuing ianalumab saw further improvement in systemic disease activity through Week 108, with no new safety findings*[1]
- *Nearly two-thirds of patients on continuous ianalumab reached low disease activity at Week 108*[1]
- *Improvements in stimulated salivary flow were maintained in patients with baseline salivary flow >0.4mL/min continuing ianalumab*[1]
- *Patients who switched from placebo to ianalumab monthly saw improvements across most efficacy outcomes, including an increase in low disease activity rates*[1]

Basel, November 10, 2026 – Novartis today presented long-term results from the ongoing NEPTUNUS extension study of ianalumab in Sjögren's disease at the American College of Rheumatology Convergence 2026. The data showed that the reduction in systemic disease activity continued to deepen from Week 48 through Week 108 among patients who continued ianalumab 300 mg monthly as measured by EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI).[1]

Improvements were also sustained in physician- and patient-reported outcomes as well as salivary flow.[1] Additionally, most efficacy outcomes improved after patients switched from placebo to ianalumab.[1] Adverse event and serious adverse event rates were comparable between the two treatment arms through Week 204, with no new safety findings.[1]

"Sjögren's disease is chronic and systemic, requiring treatment options that can provide sustained disease control over the long term," said Thomas Dörner, Department of Medicine and Clinical Immunology at Charité – Universitätsmedizin Berlin and Deutsches Rheuma-Forschungszentrum Berlin, ein Leibniz-Institut. "These data provide important new insights into long-term treatment response and deepen our understanding of the disease."

Key findings[1]

- At Week 108, ESSDAI reductions continued to deepen with longer ianalumab treatment, with a mean reduction from core-study baseline of 7.5 points in the group that continued ianalumab monthly and 6.5 points in the group that switched from placebo to ianalumab monthly at Week 60.
- Low disease activity (LDA) rates increased from 57.1% to 65.1% in the continuous ianalumab monthly group between Weeks 48 and 108. In patients who switched from placebo to ianalumab monthly at Week 60, LDA rates increased from 50.4% to 60.9%.
- Among patients with stimulated salivary flow greater than 0.4 mL/min at baseline, improvements were maintained through Week 96 in the continuous ianalumab monthly group and observed after patients switched from placebo to ianalumab at Week 60.
- Improvements in physician- and patient-reported measures and symptoms were sustained through Week 108 among patients who continued ianalumab monthly, measured by ESSPRI and SSSD, and were observed following the switch from placebo to ianalumab at Week 60.

Sjögren's disease is a serious, systemic autoimmune disease in which B-cell dysfunction plays a significant role, contributing to inflammation, tissue damage and symptoms including dryness, fatigue, pain and organ involvement, which can substantially impact patients' daily lives.[2-6] Targeted therapies are needed to address systemic disease activity, as there are no approved options currently available outside China.[7]

"These findings strengthen the growing body of evidence for ianalumab and reinforce our commitment to advancing a targeted treatment that can improve care for people living with Sjögren's disease," said Angelika Jahreis, Global Head, Development, Immunology, Novartis. "The novel dual mechanism of ianalumab is designed to target B-cell dysfunction, which plays a significant role in this complex disease."

Ianalumab is currently under review by regulatory authorities in multiple countries, including the US where a decision from the Food and Drug Administration is expected this year. The NEPTUNUS-1 and NEPTUNUS-2 studies were the first global Phase III trials to demonstrate a statistically significant reduction in Sjögren's disease activity.[8,9,10] The NEPTUNUS extension study is ongoing to continue evaluating the longer-term efficacy, safety and tolerability of ianalumab.[1,11]

About ianalumab
Ianalumab is a fully human monoclonal antibody with a novel dual mechanism of action that depletes B cells and inhibits their activation and survival via BAFF-R blockade.[12] Novartis is investigating ianalumab for its ability to treat B-cell driven diseases, including Sjögren's disease, immune thrombocytopenia (ITP), systemic lupus erythematosus (SLE), lupus nephritis (LN), and systemic sclerosis (SSc).[9-11,13-16]

About the NEPTUNUS program
NEPTUNUS-1 and NEPTUNUS-2 are global, multicenter, pivotal Phase III trials evaluating the efficacy and safety of ianalumab in people with Sjögren's disease.[9,10] NEPTUNUS-1 evaluated ianalumab 300 mg subcutaneously (s.c.) monthly versus placebo for 52 weeks, while NEPTUNUS-2 evaluated ianalumab 300 mg s.c. monthly or every three months versus placebo for up to 52 weeks.[9,10] The primary endpoint in both trials assessed improvement in systemic disease activity using ESSDAI. Participants completing the core studies were eligible to enter an ongoing NEPTUNUS extension trial evaluating the long-term efficacy, safety and tolerability of ianalumab.[11] The interim analysis of the extension trial includes patients who continued ianalumab and patients who switched from placebo to ianalumab at Week 60.[1]

About Sjögren's disease
Sjögren's disease is a complex, systemic autoimmune disease that causes inflammation and tissue damage, impacting the entire body.[5] It primarily affects exocrine glands, leading to excessive dryness, with over 90% of patients experiencing dry eyes and dry mouth.[5,6] The disease is heterogenous and inflicts a wide range of symptoms, with patients most commonly experiencing dryness, fatigue and widespread pain, though 30-40% of patients will also show extraglandular organ involvement.[17,18] The risk of lymphoma is increased in patients with Sjögren's.[17] Sjögren's affects approximately 0.25% of the population with an estimated 50% undiagnosed.[19,20] Sjögren's is nine times more common in women than men.[5]

About Novartis Immunology
At Novartis, we're advancing bold science with the goal of bringing relief and a renewed sense of hope to people living with complex and often overlooked autoimmune and other immune-mediated diseases, so they can reclaim their lives. Building on our legacy of first-in-class innovation across rheumatology, dermatology and allergy, and a diverse industry-leading pipeline, we're committed to shaping what's next in Immunology.

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future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations could be affected by, among other things, uncertainties concerning: global healthcare cost containment, including ongoing government, payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; the success of our key products, commercial priorities and strategy; research and development of new products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products; our ability to realize the strategic benefits, operational efficiencies or opportunities expected from our external business opportunities; the development or adoption of new technologies, including artificial intelligence, and new business models; potential significant breaches of information security or disruptions of our information technology systems; actual or potential legal proceedings, including regulatory actions or delays or government regulation related to the products and pipeline products described in this press release; safety, quality, data integrity, or manufacturing issues; major macroeconomic and geo- and socio-political developments, including the impact of any potential tariffs on our products or the impact of war in certain parts of the world; future global exchange rates; future demand for our products; and other risks and factors referred to in Novartis AG's most recently filed Form 20-F and in subsequent reports filed with, or furnished to, the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

About Novartis
Novartis is an innovative medicines company. Every day, we work to reimagine medicine to improve and extend people's lives so that patients, healthcare professionals and societies are empowered in the face of serious disease. Our medicines reach more than 300 million people worldwide.

Reimagine medicine with us: Visit us at **www.novartis.com** and connect with us on **LinkedIn**, **Facebook**, **X/Twitter** and **Instagram**.

References

1. Dörner T, et al. "Efficacy and Safety of ianalumab in Sjögren's disease: Long-term results from the NEPTUNUS extension study." Presented at: American College of Rheumatology Convergence 2026; Late-Breaking Abstract 2535661; Poster Session (LB01-LB18); November 10, 2026.
2. Lee AY, Qi Z, Jackson KJ, et al. Self-reactive B cells are increased in all major stages of peripheral development in Sjögren's disease. *Immunol Cell Biol*. 2025;103(4):401-410. doi:10.1111/imcb.70005
3. Both T, Dalm VA, van Hagen PM, et al. Reviewing primary Sjögren's syndrome: beyond the dryness - From pathophysiology to diagnosis and treatment. *Int J Med Sci*. 2017;14(3):191-200. doi:10.7150/ijms.17718
4. Cornec D, Devauchelle-Pensec V, Tobón GJ, et al. B cells in Sjögren's syndrome: from pathophysiology to diagnosis and treatment. *J Autoimmun*. 2012;39:161-167. doi:10.1016/j.jaut.2012.05.014
5. Negrini S, Emmi G, Greco M, et al. Sjögren's syndrome: a systemic autoimmune disease. *Clin Exp Med.* 2022; 22(1):9-25. doi:10.1007/s10238-021-00728-6
6. Maleki-Fischbach M, Kastsianok L, Koslow M, et al. Manifestations and management of Sjögren's disease. *Arthritis Res Ther.* 2024; 26(1):43. doi:10.1186/s13075-024-03262-4
7. Novartis. Ianalumab | Sjögren's disease | Global & US Story House, Version 1.1. September 30, 2026.
8. Grader-Beck T, et al. Ianalumab demonstrates significant reduction in disease activity in patients with Sjögren's Disease: Efficacy and safety results from two global Phase 3, randomized, placebo-controlled double-blind studies (NEPTUNUS-1 and NEPTUNUS-2). Presented at the American College of Rheumatology (ACR) Congress; October 24-29, 2025; Chicago, Illinois.
9. ClinicalTrials.gov NCT05350072 [Last accessed: November 2026]
10. ClinicalTrials.gov NCT0539214 [Last accessed: November 2026]
11. ClinicalTrials.gov. NCT05985915 [Last accessed: November 2026]
12. Dörner T, Bowman SJ, Fox R, et al. Safety and efficacy of ianalumab in patients with Sjögren's disease: 52-week results from a randomized, placebo-controlled, Phase 2b dose-ranging study. *Arthritis Rheumatol.* 2025; 77(5):560-570. doi:10.1002/art.43059

13. ClinicalTrials.gov NCT05653219 [Last accessed: November 2026]
14. ClinicalTrials.gov NCT05639114 [Last accessed: November 2026]
15. ClinicalTrials.gov NCT05126277 [Last accessed: November 2026]
16. ClinicalTrials.gov NCT06470048 [Last accessed: November 2026]
17. Mariette X, Criswell LA. Primary Sjögren's Syndrome. *N Engl J Med*. 2018;378(10):931-939. doi:10.1056/NEJMcp1702514
18. Gairy K, Knight C, Anthony P, et al. Burden of illness among subgroups of patients with primary Sjögren's syndrome and systemic involvement. *Rheumatology (Oxford).* 2021;60(4):1871-1881. doi:10.1093/rheumatology/keaa508
19. Conrad N, Misra S, Verbakel JY, et al. Incidence, prevalence, and co-occurrence of autoimmune disorders over time and by age, sex, and socioeconomic status: a population-based cohort study of 22 million individuals in the UK. *Lancet.* 2023;401(10391):1878-1890. doi:10.1016/S0140-6736(23)00457-9
20. Narváez J, Sánchez-Fernández SÁ, Seoane-Mato D, et al. Prevalence of Sjögren's syndrome in the general adult population in Spain: estimating the proportion of undiagnosed cases. *Sci Rep*. 2020;10(1):10627. doi:10.1038/s41598-020-67462-z

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