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NEWS RELEASE

Johnson & Johnson announces new Phase 2 nipocalimab study data in Sjögren's disease that reveal insights on importance of symptom improvements most valued by patients

2026-11-07

- New patient experience data[a] to be presented at ACR 2026 show mouth dryness was reported as the most important symptom to improve, followed by eye dryness, fatigue and joint pain
- Patient insights complement Phase 2 study results demonstrating a 50% increase in saliva production[b] in more than twice as many patients on nipocalimab compared to placebo[c]
- Two Phase 3 studies are ongoing, evaluating nipocalimab in Sjögren's disease including these measures critical to patients

NEW BRUNSWICK, N.J., Nov. 7, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new patient experience findings[a] from the Phase 2 DAHLIAS study of nipocalimab in Sjögren's disease (SjD), a chronic, systemic autoantibody-driven disease affecting approximately four million people worldwide.[1] The results show that mouth dryness is the symptom improvement that matters most to patients,[2] complementing previously reported Phase 2 study results on increased saliva production in patients who received nipocalimab.[3] This was also the most frequently reported symptom, with 96% of patients surveyed citing mouth dryness.[2] These findings helped to inform the design of the ongoing Phase 3 study of nipocalimab in SjD, and are among 23 abstracts on nipocalimab to be presented at the American College of Rheumatology (ACR) Convergence 2026.

Patient experience of Sjögren's disease reflects core symptoms including dryness and systemic manifestations

Interviews were conducted with participants following the Phase 2 study's treatment period. Five core symptoms

were most frequently reported by patients: mouth dryness (96%), fatigue (92%), eye dryness (90%), joint pain (73%) and, among women, vaginal dryness (49%). Patients who participated in the interviews reported improvements across many of these core symptoms during the treatment phase of the study.[2]

"Patients told us that Sjögren's disease affects nearly every aspect of daily life, with mouth dryness emerging as both the most frequently reported symptom and the symptom most often prioritized, among those asked, for improvement," said Ghaith Noaiseh, M.D., Associate Professor, Allergy, Clinical Immunology, and Rheumatology, The University of Kansas Medical Center.[d] "Notably, in the previously published clinical data, at least 50% improvement in objective salivary flow was observed in more than twice as many patients receiving 15 mg/kg nipocalimab compared with placebo.[c] I look forward to the Phase 3 results and what they may tell us about the potential of nipocalimab to deliver meaningful benefit for patients."

Symptom improvements were associated with tangible improvements in everyday life and functioning

Patients described the core symptoms of SjD as having far-reaching effects on physical, social and emotional well-being, with improvements in these symptoms reported to have tangible benefits in day-to-day life. These improvements are associated with positive changes in physical functioning, less need for disease management, and less interference in family, work and social commitments. Nearly three-quarters of participants (73.5%) reported being satisfied or very satisfied with study treatment.[2]

"These patient insights reinforce the broad, systemic nature of Sjögren's disease and the importance of recognizing and addressing the symptoms and outcomes that matter most to patients," said Leonard L. Dragone, M.D., Ph.D., Disease Area Leader, Autoantibody and Rheumatology, Johnson & Johnson. "Together, these findings alongside the positive Phase 2 clinical results provide important context as we advance nipocalimab as a potential targeted approach designed to address the underlying biology of this serious autoantibody-driven disease."

Following the **positive Phase 2 DAHLIAS** results, which showed nipocalimab significantly reduced disease activity and severity in patients with moderate-to-severe disease, Johnson & Johnson initiated the Phase 3 **DAFFODIL** study in adults with moderate-to-severe SjD.[3] The DAFFODIL study design reflects the need to address both the systemic nature of SjD and the outcomes patients value most by assessing disease activity alongside dryness, pain, fatigue, quality of life and patient-perceived improvement.[4]

Nipocalimab is the only Fc receptor (FcRn) blocker granted both **Breakthrough Therapy Designation** and **Fast Track Designation** by the U.S. Food and Drug Administration (FDA) for the treatment of adults with moderate-to-severe SjD.

Editor's notes:

a. Of 163 DAHLIAS participants, 49 (30.1%) – still blinded and pooled across treatment arms – completed the exit interviews. The analysis was based on 60-minute, one-to-one semi-structured qualitative exit interviews conducted within two weeks after the 24-week treatment period, using blinded, independent researchers and thematic analysis to systematically capture patient experience and perceived symptom changes.

b. Objective unstimulated salivary flow, an exploratory endpoint of the Phase 2 DAHLIAS study.

c. Data from the Phase 2 DAHLIAS study show an improvement in objective salivary flow (i.e., at least 50% increase from baseline) was observed in more than twice as many patients in the high-dose nipocalimab group (15 mg/kg) compared to the placebo group (33% versus 16%, respectively) at Week 24.

d. Ghaith Noaiseh, M.D., is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

About DAHLIAS

DAHLIAS (**NCT04968912**) is a Phase 2 multicenter, randomized, placebo-controlled, double-blind, dose-ranging study to evaluate the effects of nipocalimab in participants with moderately-to-severely active primary SjD who were seropositive for anti-Ro60 and/or anti-Ro52 immunoglobulin G (IgG) antibodies. 163 adults aged 18-75 were randomized 1:1:1 to receive intravenous nipocalimab at 5 or 15 mg/kg, or placebo every 2 weeks through Week 22 and received protocol-permitted background standard of care. Safety assessments were conducted through Week 30. The primary endpoint was change from baseline in the ClinESSDAI (Clinical European League Against Rheumatism Sjögren's Syndrome Disease Activity Index) Score at Week 24.[5]

About Sjögren's disease

Sjögren's disease (SjD) is one of the most prevalent autoantibody-driven diseases for which no therapies are currently approved that treat the underlying and systemic nature of the disease.[6] It is a chronic autoantibody-driven disease that is estimated to impact approximately four million people worldwide and is nine times more common in women than men.[1] SjD is characterized by autoantibody production, chronic inflammation, and lymphocytic infiltration of exocrine glands.[7] Most patients are affected by mucosal dryness (eyes, mouth, vagina), joint pain and fatigue.[8] More than 50% of SjD patients have a moderate-to-severe form of the condition, and cumulative disease burden can be as high as that of rheumatoid arthritis or systemic lupus erythematosus.[9,10,11] It is usually associated with impaired quality of life and, in up to approximately half of patients, a loss of functional capacity that can result in an inability to work due to a disability.[8,9,12]

About nipocalimab

Nipocalimab is an investigational immunoselective treatment designed to target, bind with high affinity, and block the neonatal Fc receptor (FcRn), reducing circulating immunoglobulin (IgG) antibodies that drive disease while also preserving B-cell function based on in vitro and/or in vivo studies.[13,14] Nipocalimab is being investigated across three key segments in the autoantibody space including Rheumatologic disease, Rare Autoantibody diseases, and Maternal Fetal diseases mediated by maternal alloantibodies in which blockade of IgG binding to FcRn in the placenta is believed to limit transplacental transfer of maternal alloantibodies to the fetus.[4,15,16,17,18,19,20,21,22]

The U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have granted several key designations to nipocalimab including:

- EU EMA Orphan medicinal product designation for hemolytic disease of the fetus and newborn (HDFN) in October 2019 and fetal and neonatal alloimmune thrombocytopenia (FNAIT) in April 2025
- U.S. FDA Fast Track designation in HDFN and warm autoimmune hemolytic anemia (wAIHA) in July 2019, generalized myasthenia gravis (gMG) in December 2021, FNAIT in March 2024, Sjögren's disease (SjD) in March 2025, and systemic lupus erythematosus (SLE) in January 2026
- U.S. FDA Orphan drug status for wAIHA in December 2019, HDFN in June 2020, gMG in February 2021, chronic inflammatory demyelinating polyneuropathy (CIDP) in October 2021 and FNAIT in December 2023
- U.S. FDA Breakthrough Therapy designation for HDFN in February 2024 and for SjD in November 2024
- U.S. FDA granted Priority Review in gMG in Q4 2024 and wAIHA in Q2 2026

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CAUTIONS CONCERNING FORWARD-LOOKING STATEMENTS

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of nipocalimab. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at **www.sec.gov**, **www.jnj.com**, investor.jnj.com or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

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