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NEWS RELEASE

Johnson & Johnson presents new data further reinforcing the role of nipocalimab in lowering the autoantibodies driving Sjögren's disease

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- Nipocalimab, an immunoselective neonatal Fc receptor (FcRn) blocker, is designed to target and reduce pathogenic immunoglobulin G (IgG) autoantibodies associated with Sjögren's disease while preserving immune function
- New exploratory analysis of Phase 2 study data shows a strong correlation between autoantibody levels and even greater clinical response rates of participants in the nipocalimab treatment group
- Previously reported data from the Phase 2 study showed nipocalimab reduced Sjögren's disease activity and severity, with potential to address systemic manifestations and the most burdensome patient-reported symptoms including dryness, fatigue and pain
- Nipocalimab is the only FcRn blocker granted both Breakthrough Therapy Designation and Fast Track Designation by the U.S. FDA for the treatment of adults with moderate-to-severe Sjögren's disease.

LONDON, June 3, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new biomarker exploratory analyses from the Phase 2 DAHLIAS study evaluating nipocalimab in adults with moderate-to-severe Sjögren's disease (SjD)[a] showing that participants with elevated autoantibody and immunoglobulin G (IgG) levels[b], who are often those who experience more substantial disease burden, showed greater clinical response rates.[1] These data will be presented in an oral session at the 2026 European Alliance of Associations for Rheumatology (EULAR) Congress.

A healthcare professional's perspective

"Sjögren's disease is a highly heterogeneous condition that has historically posed significant challenges for therapeutic development, leaving gaps in patient care," said R. Hal Scofield, M.D., the University of Oklahoma and

Oklahoma Medical Research Foundation.[c] "These analyses provide important insight into the potential role of pathogenic immunoglobulin G autoantibodies in disease activity and help expand our understanding of the biological drivers of Sjögren's disease for certain patients. This research is critical for helping clinicians evaluate emerging evidence and the evolving treatment landscape in this chronic, underserved disease."

New DAHLIAS Phase 2 clinical and biomarker findings

Clinical improvements were observed across all patients, with the greatest responses observed in participants with elevated known disease-driving autoantibodies and IgG levels – factors associated with more severe SjD activity and outcomes.[1] Previously reported **positive Phase 2 study results** demonstrated statistically significant improvement in ClinESSDAI[d] scores with nipocalimab versus placebo.[2] In the current analysis, patients in the autoantibody-high subgroup[b] treated with nipocalimab achieved higher response rates than observed in the overall participant population (62.5% versus 51.9%).[1] These data support the continued investigation of nipocalimab as a potential immunoselective approach for systemic SjD management in the ongoing **Phase 3 DAFFODIL** study.

Biomarker analyses reveal autoantibody and immune function insights

These findings further support the underlying mechanism of action of nipocalimab as a targeted, immunoselective approach designed to reduce pathogenic IgG autoantibodies associated with SjD disease activity while preserving broader immune function.[3]

"The biomarker analyses are consistent with the hypothesized mechanism of nipocalimab in Sjögren's disease. These findings suggest greater response in the broad study population of adults with moderate-to-severe Sjögren's disease, plus a greater response observed among patients with elevated disease-driving autoantibodies and immunoglobulin G levels," said Leonard L. Dragone, M.D., Ph.D., Disease Area Leader, Autoantibody and Rheumatology, Johnson & Johnson. "The data also furthers our understanding of the role pathogenic IgG autoantibodies may play in this heterogenous disease as we continue to investigate nipocalimab in Sjögren's."

Editor's Notes:

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a. Nipocalimab is not FDA approved for the treatment of SjD.
b. Subgroup included patients with moderate-to-severe SjD who had the highest baseline levels of three disease-associated autoantibodies – anti-Ro60, anti-Ro52 and anti-La – measured in the study population.
c. Dr. Scofield is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.
d. ClinESSDAI is an endpoint specific to SjD and is a composite scale that assesses organ disease activity across 11 organ system domains [cutaneous, pulmonary, renal, articular, muscular, peripheral nervous system (PNS), central nervous system (CNS), hematological, glandular, constitutional, lymphadenopathy and lymphoma; a higher score indicates greater symptom severity.

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 Sjögren's disease (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 in baseline in the ClinESSDAI (Clinical European League Against Rheumatism Sjögren's Syndrome Disease Activity Index) Score at Week 24.[4]

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.[5] It is a chronic autoimmune disease that is estimated to impact approximately four million people worldwide and is nine times more common in women than men.[6] 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 disease burden can be as high as that of rheumatoid arthritis or systemic lupus erythematosus (SLE).[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.[10,11,12]

ABOUT NIPOCALIMAB

Nipocalimab is an investigational immunoselective treatment designed to target, bind with high affinity and block neonatal Fc receptor (FcRn), reducing circulating immunoglobulin (IgG) antibodies that drive disease while also preserving key immune functions.[13,14] Nipocalimab is being investigated across three key segments in the autoantibody space including Rheumatologic diseases, Rare Autoantibody diseases andMaternal Fetal diseases mediated by maternal alloantibodies in which blockade of IgG binding to FcRn in the placenta is also 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

ABOUT JOHNSON & JOHNSON

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow and profoundly impact health for humanity.

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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** 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.

[1] Scofield, H et al. Biomarker-Driven Insights to Clinical Response in DAHLIAS: A Nipocalimab Trial for Sjogren's Disease. Presented at the 2026 European Alliance of Associations for Rheumatology (EULAR) Congress. Oral Presentation #OP0131

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