Johnson&Johnson

NEWS RELEASE

Johnson & Johnson unveils new data showing nipocalimab is the first and only investigational FcRn blocker with potential to reduce systemic lupus erythematosus (SLE) activity in a Phase 2 study

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The JASMINE study met the primary endpoint and key secondary and exploratory endpoints, including those indicating the potential of nipocalimab for steroid sparing

SLE is one of the most prevalent and debilitating autoantibody diseases, causing one's own immune system to mistakenly attack various tissues, which can lead to potentially life-threatening systemic organ damage

Based on these positive topline results, the company plans to initiate a Phase 3 program for nipocalimab in SLE

SPRING HOUSE, Pa., Jan. 6, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced positive topline results from the Phase 2b JASMINE (**NCT04882878**) study of adults living with systemic lupus erythematosus (SLE) and the initiation of a Phase 3 program. The JASMINE study met the primary endpoint (percentage of patients achieving Systemic Lupus Erythematosus Responder Index [SRI-4][a] composite response at Week 24 with statistical significance compared with placebo), and key secondary and exploratory endpoints, including those indicating the potential of nipocalimab for steroid sparing. Nipocalimab had a safety and tolerability profile consistent with previous Phase 2 studies, with no new safety signals identified.

These data represent the first positive results of an investigational FcRn blocker treatment in this chronic, debilitating autoantibody-driven disease that impacts an estimated 3 to 5 million people worldwide, and 450,000 in the U.S.[1,2] Chronic symptoms of SLE include severe fatigue, joint pain and swelling, and rashes, including a hallmark butterfly-shaped facial rash.[3]

JASMINE is a 52-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group, dose-ranging study of nipocalimab in 228 adult participants with active SLE and the first positive study of an FcRn blocker for the treatment of active SLE.[4]

"Systemic lupus erythematosus or SLE is a serious autoantibody-driven disease that can impact multiple organ systems, significantly reducing health-related quality of life for millions of people," said Leonard L. Dragone, M.D., Ph.D., Disease Area Leader, Autoantibody and Rheumatology, Johnson & Johnson Innovative Medicine. "Many people living with SLE also face complications associated with long-term steroid use, underscoring the limitations of current treatment approaches and the critical need for immunoselective therapies that are safe, tolerable, and capable of reducing disease activity, while preserving immune function."

Full results from the JASMINE study will be presented at a future medical congress.

Editor's note:

a. The SLE Responder Index 4 (SRI-4) is a composite measure used to assess treatment response in patients with SLE during clinical studies. It comprises criteria from three different internationally validated indices, SELENA-SLE Disease Activity Index (SELENA-SLEDAI), Physician Global Assessment (PGA) and the British Isles Lupus Assessment Group (BILAG) 2004.

ABOUT JASMINE

JASMINE (**NCT04882878**) is a 52-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group, dose-ranging study of nipocalimab in 228 adult participants with active SLE and the first positive study of an FcRn blocker for the treatment of active SLE.[4]

ABOUT SYSTEMIC LUPUS ERYTHEMATOSUS

Systemic Lupus Erythematosus (SLE) is a chronic autoimmune disease that occurs when the body's immune system mistakenly attacks its own healthy tissues. This can lead to inflammation and damage in many parts of the body, including the skin, joints, heart, lungs, kidneys, and brain.[5] SLE affects nine times more women than men, often striking initially between the ages of 15-44.[6] In addition to systemic organ damage, other complications of SLE can include end-stage renal failure, scarring cutaneous lesions, neurological damage, and various forms of cardiovascular disease.[5] People living with SLE often face reduced health-related quality of life, due to severe fatigue, mood disturbances, joint pain and swelling, and rashes, including the hallmark butterfly-shaped facial rash, as well as complications of long-term glucocorticoid use.[3] Severe fatigue is the most widely reported and

debilitating symptom of SLE, affecting up to 80% of people with SLE.[7] SLE is the most common form of lupus, affecting 3 to 5 million people worldwide, approximately 70% of lupus cases.[1,6] It is estimated that 450,000 people in the United States are affected by SLE.[2]

ABOUT NIPOCALIMAB

Nipocalimab is an investigational monoclonal antibody, designed to bind with high affinity to block FcRn and reduce levels of circulating immunoglobulin G (IgG) antibodies potentially without additional detectable effects on other adaptive and innate immune functions. This includes autoantibodies and alloantibodies that underlie multiple conditions across three key segments in the autoantibody space including Rare Autoantibody diseases, Maternal Fetal diseases mediated by maternal alloantibodies and autoantibody-driven Rheumatic diseases.[8,9,10,11,12,13,14,15,16] Blockade of IgG binding to FcRn in the placenta is also believed to limit transplacental transfer of maternal alloantibodies to the fetus.[17,18]

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, gMG in December 2021, FNAIT in March 2024 and Sjögren's disease (SjD) in March 2025
- 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 Sjögren's disease in November 2024
- U.S. FDA granted Priority Review in generalized myasthenia gravis in Q4 2024

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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Janssen Research & Development, LLC, Janssen Biotech, Inc. and Janssen Global Services, LLC are Johnson & Johnson companies.

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.

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[12] **ClinicalTrials.gov** Identifier: NCT05912517. Available at: **https://www.clinicaltrials.gov/study/NCT05912517**. Last accessed: January 2026.

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[16] **ClinicalTrials.gov** Identifier: NCT06533098. Available at: **https://clinicaltrials.gov/ct2/show/NCT06533098**. Last accessed: January 2026.

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