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NEWS RELEASE

Johnson & Johnson late-breaking results show nipocalimab significantly reduced systemic lupus erythematosus (SLE) disease activity in a Phase 2 study

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- Nipocalimab – the first and only neonatal Fc receptor (FcRn) blocker to be studied in systemic lupus erythematosus – is designed to target and reduce pathogenic immunoglobulin G (IgG) autoantibodies associated with this disease while preserving immune function
- Results demonstrated significant reduction of systemic lupus erythematosus disease activity which continued beyond the 24-week primary endpoint, and were sustained through Week 52 in the nipocalimab 15 mg/kg group[a]
- The ongoing Phase 3 study of nipocalimab is currently recruiting people living with systemic lupus erythematosus – a debilitating autoantibody-driven disease which can lead to systemic organ damage

LONDON, June 3, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced nipocalimab met the primary endpoint of decreasing disease activity at 24 weeks as measured by SLE Responder Index 4 (SRI-4)[b] and continued to demonstrate sustained reduction in disease activity in adults with moderate-to-severe systemic lupus erythematosus (SLE)[a] through 52 weeks in the Phase 2 JASMINE study as measured by both SRI-4[b] and Lupus Low Disease Activity State (LLDAS).[c] In addition, the study results showed greater response versus placebo plus background medication[d] in participants who tested positive for lupus-associated autoantibodies, which represents the vast majority (~80%) of people living with SLE.[e,1] These findings will be featured in a late-breaking presentation at the European Alliance of Associations for Rheumatology (EULAR) 2026 Congress in London and are among the 38 abstracts the Company is presenting across its Rheumatology portfolio.

Nipocalimab is designed to selectively block the neonatal Fc receptor (FcRn), reducing levels of circulating

pathogenic immunoglobulin (IgG) autoantibodies and immune complexes associated with inflammation in SLE.[2,3] By reducing circulating IgG, including autoantibodies, nipocalimab is designed to target the underlying cause of disease while preserving critical immune functions.[4] JASMINE is the first clinical study to demonstrate efficacy of FcRn blockade in SLE and provides clinical, biomarker and pharmacodynamic evidence supporting the continued investigation of nipocalimab as a potential treatment option for this disease.[5]

A healthcare professional's perspective

"The consistent improvements observed across established disease activity measures and reductions in pathogenic immunoglobulin G autoantibodies are encouraging and support the continued investigation of nipocalimab as a targeted treatment approach for people living with systemic lupus erythematosus," said Richard Furie, M.D., Chief of the Division of Rheumatology at Northwell.[f] "These 52-week findings support the potential of nipocalimab to provide disease control over time for a broad population of autoantibody-positive adult patients living with moderate-to-severe systemic lupus erythematosus, a disease in which many patients experience ongoing disease activity and risk of irreversible organ damage."

JASMINE Phase 2 clinical findings

The Phase 2 JASMINE study is the first proof-of-concept for a FcRn-blocker in SLE and demonstrates the potential of nipocalimab to reduce disease activity, with greater responses observed in autoantibody-positive patients.[1,5]

- The study met its primary endpoint at Week 24, with a greater proportion of patients receiving nipocalimab 15 mg/kg plus background medication achieving an SRI-4[b] response compared with placebo plus background medication (53.5% vs 46.7%).
- In a predefined autoantibody-positive patient population[e], greater SRI-4 response rates were observed (58.2% vs. 36.1%) and greater achievement of LLDAS (38.9% vs. 18.0%) compared with placebo plus background medication at Week 52.
- At Week 52, a key secondary endpoint, 53.6% of patients receiving nipocalimab 15 mg/kg achieved an SRI-4[b] response, compared with 39.7% for placebo plus background medication.
- More patients receiving nipocalimab 15 mg/kg also achieved LLDAS[c], a key exploratory endpoint that enables a treat-to-target[g] approach, compared with placebo plus background medication (37.5% vs. 20.5%) at Week 52.

Nipocalimab had a safety profile consistent with previous studies of nipocalimab and no new safety signals were identified. The most common adverse reactions in patients with SLE treated with nipocalimab (≥10%) were nasopharyngitis, headache, urinary tract infection and nausea.[5]

"The JASMINE results provide important new insights into the potential of nipocalimab for adults with moderate-to-severe systemic lupus erythematosus as we continue advancing this program," said Leonard L. Dragone, M.D.,

Ph.D., Disease Area Leader, Autoantibody and Rheumatology, Johnson & Johnson. "We are especially encouraged by the responses observed in autoantibody-positive study participants. These findings support the potential of nipocalimab as a targeted, immunoselective treatment designed to address underlying drivers of systemic lupus erythematosus."

Nipocalimab received **Fast Track Designation** in SLE by the U.S. Food and Drug Administration (FDA) earlier this year. The ongoing **Phase 3 GARDENIA study** is currently recruiting.

Editor's Notes:

a. Nipocalimab is not FDA-approved for SLE.

b. The 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.

c. LLDAS definition: (1) SLE Disease Activity Index (SLEDAI)-2K ≤4, with no activity in major organ systems (renal, central nervous system (CNS), cardiopulmonary, vasculitis, fever) and no hemolytic anemia or gastrointestinal activity; (2) no new lupus disease activity compared with the previous assessment; (3) a Safety of Estrogens in Lupus Erythematosus National Assessment (SELENA)-SLEDAI physician global assessment (scale 0-3) ≤1; (4) a current prednisolone (or equivalent) dose ≤7.5 mg daily; and (5) well-tolerated standard maintenance doses of immunosuppressive drugs and approved biological agents.

d. Protocol-permitted background medications include oral corticosteroids, antimalarials and no more than two of the following immunomodulatory drugs: azathioprine, mycophenolate mofetil, mycophenolic acid, oral methotrexate.

e. The autoantibody-positive population was defined as participants who met ≥1 of the following during screening: (1) positive anti-double-stranded DNA (anti-dsDNA), (2) positive anti-Smith, (3) positive antinuclear antibodies (ANA) and positive for anti-Ro, anti-RNP or had a history of anti-dsDNA.

f. Dr. Richard Furie has provided consulting, advisory and speaking services to Johnson & Johnson. He has not been paid for any media work.

g. Treat-to-target in SLE is a therapeutic strategy in which treatment is guided by regular assessment of disease activity and adjusted to achieve a predefined target – primarily remission, or low disease activity if remission is not attainable – to improve long-term outcomes and prevent organ damage.[6]

ABOUT JASMINE

JASMINE (**NCT04882878**) is a Phase 2, multicenter, randomized, double-blind, placebo-controlled, parallel-group, dose-ranging study to evaluate nipocalimab in 228 adult participants with active systemic lupus erythematosus (SLE). Adults aged 18-65 years with moderate-to-severe SLE, defined by established measures of disease activity, who were positive for antinuclear antibodies (ANA), anti-double-stranded DNA (anti-dsDNA), and/or anti-Smith antibodies, and had not responded to at least one standard-of-care treatment were enrolled. Participants were randomized 1:1:1 to receive intravenous nipocalimab at 5 or 15 mg/kg, or placebo every 2 weeks through Week 52, in addition to protocol-permitted background medications. The primary endpoint was the SLE Responder Index-4 (SRI-4) composite response at Week 24. Pharmacodynamic effects and safety, including adverse events, were assessed through Week 58.[5]

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.[7,8] This can lead to inflammation and damage in many parts of the body, including the skin, joints, heart, lungs, kidneys and brain.[3] SLE affects nine times more women than men, often striking initially between the ages of 15-44.[9] 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.[3] People living with SLE often face reduced health-related quality of life, due to severe fatigue, mood disturbances, joint pain, swelling and rashes, including the hallmark butterfly-shaped facial rash, as well as complications of long-term glucocorticoid use.[10] Severe fatigue is the most widely reported and debilitating symptom of SLE, affecting up to 80% of people with SLE.[11] SLE is the most common form of lupus, affecting 3 to 5 million people worldwide, approximately 70% of lupus cases.[12,13] It is estimated that 450,000 people in the United States are affected by SLE.[14]

ABOUT NIPOCALIMAB

Nipocalimab is an investigational immunoselective treatment designed to target, bind with high affinity, and block neonatal Fc receptor (FcRn), reducing circulating immunoglobulin G (IgG) antibodies that drive disease while also preserving key immune functions.[2,3] 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 also believed to limit transplacental transfer of maternal alloantibodies to the fetus.[5,15,16,17,18,19,20,21,22,23]

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 in 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.

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