Johnson&Johnson

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# Johnson & Johnson therapy nipocalimab granted U.S. FDA Fast Track designation in systemic lupus erythematosus (SLE)

*Fast Track designation reflects the unmet need in this serious disease and enables the potential for an accelerated FDA review timeline*

*The designation is supported by a Phase 2 study in which nipocalimab demonstrated reduction in lupus disease activity and potential for steroid sparing*

*Systemic lupus erythematosus is a debilitating, chronic autoantibody-driven disease affecting multiple organs, with limited treatment options and risk of irreversible organ damage*

*Johnson & Johnson is actively enrolling patients in a Phase 3 study of adults with active systemic lupus erythematosus*

**SPRING HOUSE, Pa., (March 3, 2026)** – Johnson & Johnson (NYSE: JNJ) today announced that nipocalimab[a] was granted U.S. Food and Drug Administration (FDA) Fast Track designation as a potential treatment for adults with systemic lupus erythematosus (SLE), a debilitating autoantibody-driven disease that impacts approximately 3 to 5 million people worldwide.[1] The U.S. FDA's Fast Track designation program is designed to expedite the development and review timelines of drugs that demonstrate the potential to treat serious conditions, aiming to deliver therapeutics to patients more quickly in areas, like SLE, where unmet needs remain.[2]

"Nipocalimab earning its fifth FDA Fast Track designation, now in systemic lupus erythematosus, reflects the importance of accelerating the delivery of an immunoselective therapy that could fill an unmet need in this serious condition," said Leonard L. Dragone, M.D., Ph.D., Disease Area Leader, Autoantibody and Rheumatology, Johnson & Johnson. "This is an important step in our efforts to help address the ongoing burden faced by people living with this debilitating disease. Through close collaboration with the FDA, we seek to advance the development of nipocalimab as a potential new treatment option for the SLE patient community."

SLE affects multiple organs including the skin, joints, kidneys, blood and central nervous systems, with associated chronic signs and symptoms including severe fatigue, pain, swelling and rashes.[3] Patients are at risk of irreversible organ damage due to systemic inflammation, disease flares and a reliance on steroids.[4] These factors can significantly reduce quality of life, which highlights the critical unmet need for additional treatment options. Nipocalimab is an immunoselective investigational therapy that lowers harmful immunoglobulin G (IgG), one of the root causes of autoantibody-driven diseases, while also preserving critical immune functions.

"Systemic lupus erythematosus is a serious, complex disease that affects many aspects of a patient's life, and treatment options remain limited," said Richard Furie, M.D., Chief of the Division of Rheumatology at Northwell Health.[b] "Progress like this brings renewed hope for more targeted therapies and meaningful outcomes for people living with this devastating disease."

Following the positive Phase 2b JASMINE results, Johnson & Johnson initiated patient enrollment for the Phase 3 GARDENIA study of adults with active SLE. Nipocalimab is the only FcRn blocker to demonstrate reduction in SLE disease activity, as shown in the JASMINE study. The study met the primary endpoint and key secondary and exploratory endpoints, including those indicating the potential of nipocalimab for steroid sparing.[5]

Editor's notes:

a. Nipocalimab is not approved in SLE.
b. Dr. Richard Furie has provided consulting, advisory and speaking services to Johnson & Johnson. He has not been paid for any media work.

**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.[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. This can lead to inflammation and damage in many parts of the body, including the skin, joints, heart, lungs, kidneys, and brain.[4] 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.[4] 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.[Error! Bookmark not defined.] 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.[Error! Bookmark not defined.,6] It is estimated that 450,000 people in the United States are affected by SLE.[8]

**ABOUT NIPOCALIMAB**
Nipocalimab is an investigational immunoselective treatment designed to target, bind with high affinity, and block FcRn, reducing circulating IgG antibodies that drive disease while also preserving key immune functions. Nipocalimab is being investigated across three key segments in the autoantibody space including Rheumatologic disease, Rare Autoantibody diseases, 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.[9,10,11,12,13,14,15,16,17,18]

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, 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 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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