Johnson&Johnson

NEWS RELEASE

Nipocalimab, the first and only investigational treatment to be granted U.S. FDA Breakthrough Therapy designation for the treatment of adults with moderate-to-severe Sjögren's disease, has now received Fast Track designation

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Sjögren's disease (SjD) is a prevalent, debilitating autoantibody disease with no FDA-approved advanced treatments

The Company is actively enrolling patients in the Phase 3 DAFFODIL study

This marks the fourth nipocalimab FDA Fast Track designation

SPRING HOUSE, Pa., March 18, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced that the U.S. Food and Drug Administration (FDA) has granted investigational nipocalimab Fast Track designation (FTD) for the treatment of adult patients with moderate-to-severe Sjögren's disease (SjD), having previously been granted **Breakthrough** Therapy designation (BTD) for the investigational therapy late last year. Currently, no advanced therapies are approved to treat this disease.

Building upon the BTD, which nipocalimab is the first and only therapeutic to receive for SjD, the U.S. FDA's FTD is also designed to accelerate the delivery of new therapeutics to patients by facilitating the development and expediting the review of drugs that demonstrate the potential to treat serious conditions and help address unmet needs for serious or life-threatening conditions.

"This marks an additional important step forward in our efforts to bring meaningful advancements to people living

with Sjögren's disease, a serious and debilitating condition. We look forward to continuing to work closely with the FDA to advance the clinical development of nipocalimab and potentially provide a much-needed treatment option for this community," said Katie Abouzahr, M.D., Vice President, Autoantibody Portfolio and Maternal Fetal Disease Area Leader, Johnson & Johnson Innovative Medicine.

There are no FDA-approved treatments that directly address the underlying causes of this complex disease, associated with serious health consequences including chronic dryness of moisture producing glands that may lead to systemic complications such as joint pain, fatigue and inflammation in multiple organ systems.[1,2,3] These systemic complications can lead to an increased risk of mortality and associated health conditions, including a 20 times greater risk of developing B-cell lymphomas when compared to the general population.[1,4]

The Phase 2 DAHLIAS study, the **results of which were presented last year**, represented the first-ever positive results of an investigational FcRn blocker as a potential targeted therapy in SjD. **The study** achieved the primary endpoint in the 15 mg/kg Q2W nipocalimab group, showing a greater than 70% relative average improvement in systemic disease activity at Week 24 compared to placebo and IgG reductions of more than 77%.[5] Trends of improvement were similarly observed across multiple secondary endpoints.[5] Safety and tolerability were consistent with other nipocalimab clinical studies.[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.[1] 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.[6,7] SjD is characterized by autoantibody production, chronic inflammation, and lymphocytic infiltration of exocrine glands. Most patients are affected by mucosal dryness (eyes, mouth, vagina), joint pain and fatigue.[1] 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. It is usually associated with impaired quality of life and functional capacity.[6,8,9]

ABOUT DAHLIAS

DAHLIAS (**NCT04968912**) is a Phase 2 multicenter, randomized, placebo-controlled double-blind study to evaluate the effects of nipocalimab in participants with primary Sjögren's disease. DAHLIAS is a Phase 2 dose-ranging study for adults with moderately-to-severely active primary SjD who were seropositive for anti-Ro60 and/or anti-Ro52 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. ClinESSDAI is a systemic diseases activity index designed to measure disease activity in patients with primary SjD based on 11 domains including: constitutional, lymphadenopathy, glandular, articular, cutaneous, respiratory, renal, muscular, peripheral nervous system, central nervous system, and hematological.

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 impact on other 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 Rheumatic diseases.[5,10,11,12,13,14,15,16.17] Blockade of IgG binding to FcRn in the placenta is also believed to limit transplacental transfer of maternal alloantibodies to the fetus.[18,19]

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

- U.S. FDA Fast Track designation in hemolytic disease of the fetus and newborn (HDFN) and warm autoimmune hemolytic anemia (wAIHA) in July 2019, gMG in December 2021 and fetal neonatal alloimmune thrombocytopenia (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 gMG in Q4 2024
- EU EMA Orphan medicinal product designation for HDFN in October 2019

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 Janssen Research & Development, LLC, Janssen Biotech, Inc. and/or 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. None of Janssen Research & Development, LLC, Janssen Biotech, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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