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For Immediate Release

Late-breaking results show nipocalimab significantly improves Sjögren's disease activity in a Phase 2 study

Patients who received nipocalimab 15 mg/kg demonstrated a greater than 70 percent relative average improvement on the primary endpoint compared to patients who received placebo

Sjögren's disease is a chronic, debilitating, and prevalent autoantibody disease with no approved advanced treatments

VIENNA (PRNewswire (June 15, 2024)) – Johnson & Johnson (NYSE: JNJ) announces patients treated with nipocalimab demonstrated statistically significant (*P*=0.002) and clinically meaningful improvement in ClinESSDAI[a] score versus placebo at 24 weeks compared to baseline (primary endpoint) in the Phase 2 DAHLIAS dose-ranging study of nipocalimab in adult patients living with Sjögren's disease (SjD). Response was demonstrated as early as Week 4 and continued to increase throughout the 24-week treatment period compared with patients receiving placebo. These data represent the first positive results in SjD for nipocalimab. The study results were featured in a late-breaking presentation (LBA0010) and are among 30 abstracts that the Company is presenting at the European Alliance of Associations for Rheumatology (EULAR) 2024 Congress.

"These data establish proof of concept for nipocalimab in Sjögren's disease and support further clinical development, which is welcome news for the approximately four million people worldwide living with this chronic, debilitating disease," said Prof. Jacques-Eric Gottenberg, M.D., Ph.D., Department of Rheumatology, Strasbourg University Hospital, National Centre for Rare Systemic Autoimmune Diseases and study investigator.[b,1,2] "SjD patients need approved advanced therapies that can help address the serious health consequences of the disease, and I am encouraged by these results and the positive impact on disease measures that are clinically meaningful."

In addition to achieving the primary endpoint, the nipocalimab 15 mg/kg treatment group demonstrated:

- Clinically meaningful improvements in secondary endpoints at Week 24 including multiple organ assessments (DAL[c]), physician assessments (PhGA[d]), and composite tools for clinical trial endpoints (STAR[e], CRESS[f])
- Improvement trends in important SjD symptoms including mouth dryness, eye dryness, and vaginal dryness
- Safety and tolerability consistent with other nipocalimab clinical studies

Furthermore, lowering levels of total IgG and autoantibodies associated with SjD (e.g. anti-Ro60 and -La/SSB) are highly consistent with the nipocalimab mechanism of action, exhibiting reductions similar to those observed in prior nipocalimab clinical studies.

"A clear need exists for patients living with Sjögren's disease to have advanced therapies that target the underlying cause and systemic nature of this disease, as none have been approved to date," said Terence Rooney, Vice President, Rheumatology, Immunology Disease Area Leader, Johnson & Johnson Innovative Medicine. "Johnson & Johnson is committed to delivering innovative and transformational approaches for autoantibody-mediated diseases like SjD, and the data presented at EULAR demonstrate the potential of nipocalimab in a disease where patients have very few options."

Editor's Note:

a. 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.

b. Prof. Jacques-Eric Gottenberg, M.D., Ph.D. is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.
c. Disease Activity Level (DAL) response is a reduction from baseline in disease activity level by at least 1 level in at least 1 clinESSDAI domain (eg, articular, hematological, cutaneous, constitutional, etc).
d. The Physician Global Assessment of Disease Severity (PhGA) is recorded by the investigator, independent of study participants' assessment, on a visual analog scale (VAS) with responses ranging from 0 to 100 mm, with the anchors "No Sjögren's Syndrome Activity" (0) at one end of the scale and "Extremely Active Sjögren's Syndrome" (100 mm) at the opposite end of the scale. The baseline measurement for the PhGA is defined as the closest measurement taken prior to the initiation of the Week 0 administration.
e. Sjögren's Tool for Assessing Response (STAR) is a composite responder index that includes all main SjD disease features, including systemic disease activity, patient-reported symptoms, tear gland item, salivary gland item and serology, in a single tool.
f. Composite of Relevant Endpoints for Sjögren's Syndrome (CRESS) is a composite endpoint tool consisting of five complementary items, systemic disease activity, patient-reported symptoms, tear gland item, salivary gland item and serology, for use in trials of primary SjD.

About Sjögren's Disease (SjD)

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.[3] 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.[1,2] SjD is characterized by autoantibody production, chronic inflammation, and lymphocytic infiltration of exocrine glandular systems. Most patients are affected by mucosal dryness (eyes, mouth, vagina), joint pain and fatigue.[3] Extraglandular manifestations are common and may impact multiple organ systems, including joints, lungs, kidneys, and nervous system.[5] Patients with SjD have a high risk of developing numerous associated conditions, including up to 20 times higher risk of developing B-cell lymphomas when compared to the general population. SjD increases all-cause mortality risk by approximately 50% more than the general population, and high activity in more than one organ/disease domain increases mortality risk by up to five-fold.[3,4] 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.[2,5]

About DAHLIAS

DAHLIAS 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 includes 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. One hundred sixty three 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.

About Nipocalimab

Nipocalimab is an investigational monoclonal antibody, purposefully designed to bind with high affinity to block FcRn and reduce levels of circulating immunoglobulin G (IgG) antibodies, while preserving immune function without causing broad immunosuppression. 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 Prevalent Rheumatology.[6,7,8,9,10,11,12,13,14]
Blockade of IgG binding to FcRn in the placenta is also believed to prevent transplacental transfer of maternal alloantibodies to the fetus.[15,16]

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

- Fast Track designation in HDFN and warm autoimmune hemolytic anemia (wAIHA) in July 2019, gMG in December 2021 and fetal neonatal alloimmune thrombocytopenia (FNAIT) in March 2024
- 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
- Breakthrough Therapy Designation for HDFN in February 2024
- Orphan medicinal product designation for HDFN by the European Medicines Agency 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. Learn more at https://www.jnj.com/ or at www.janssen.com/johnson-johnson-innovative-medicine. Follow us at @JanssenUS and @JNJInnovMed.

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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 Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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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Source: Johnson & Johnson

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