Johnson&Johnson

NEWS RELEASE

IMAAVY® (nipocalimab-aahu) demonstrates durable hemoglobin response and rapid onset of effect in pivotal Phase 2/3 study in warm autoimmune hemolytic anemia (wAIHA), an autoantibody-driven disease with no FDA-approved therapies

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- Patients in the IMAAVY 30 mg/kg treatment group[a] achieved statistically significant durable hemoglobin response[b], with mean hemoglobin improvement of at least 1 g/dL as early as Week 1[c]
- More patients treated with IMAAVY experienced improvement in fatigue[d] and corticosteroid dose reductions[e]
- IMAAVY is designed to target pathogenic immunoglobulin G (IgG) autoantibodies in warm autoimmune hemolytic anemia while preserving immune function
- Pivotal results will be presented at EHA 2026

STOCKHOLM, June 11, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today is presenting the first comprehensive results from the Phase 2/3 ENERGY study showing that IMAAVY® (nipocalimab-aahu) produced a statistically significant durable hemoglobin (Hgb) response[b] with rapid onset of effect in patients with warm autoimmune hemolytic anemia (wAIHA)[e] in the 30 mg/kg treatment group,[a] compared with those who received placebo. The randomized, placebo-controlled trial demonstrated approximately three times as many patients achieved durable Hgb levels versus placebo by 24 weeks. Overall, patients treated with this dose of IMAAVY showed a mean Hgb improvement of at least 1g/dL as early as Week 1.[1,c]

To be presented at the European Hematology Association (EHA) 2026 Congress, these results mark an important step forward for people living with wAIHA, a rare, life-threatening condition for which patients currently have no U.S. Food and Drug Administration (FDA)-approved treatment options.

"These data from the Phase 2/3 ENERGY study showed the rapid onset of effect and durable improvement in anemia which occurs by targeting the autoantibody-mediated destruction of red blood cells in people living with warm autoimmune hemolytic anemia," said Bruno Fattizzo, M.D., Assistant Professor at the Department of Oncology and Hematology-Oncology, University of Milan, Italy.[g] "Achieving hemoglobin improvements this quickly and at this scale is important in clinical practice, as it could help improve the debilitating fatigue that people living with warm autoimmune hemolytic anemia experience."

Key findings from the Phase 2/3 ENERGY study

The ENERGY study compared IMAAVY to placebo in achieving the primary endpoint of durable Hgb improvement, which was defined as achieving the following stringent criteria[1]:

- An increase from baseline in Hgb ≥2 g/dL
- Hgb concentration ≥10 g/dL
- For at least three visits (≥28 days, where criteria was met, starting by Week 16)
- Without the need for rescue therapy or changes to background medications for wAIHA

In the 30 mg/kg treatment group, a mean increase of 1 g/dL in Hgb was observed at Week 1, compared to no change in the placebo group.[c] In wAIHA, treatment also aims to maintain Hgb ≥10 g/dL and achieve a ≥2 g/dL increase from baseline and nearly two-thirds of patients achieved both of these targets by Week 24.

IMAAVY was also associated with improvements in fatigue[d] and reduction in steroid use[f], two key secondary endpoints. Changes in patient-reported fatigue were observed as early as Week 2 and sustained throughout the 24-week treatment period.[d]

In the study, IMAAVY demonstrated a safety profile consistent with the established safety profile of IMAAVY in the approved indication of generalized myasthenia gravis. The most common adverse reactions (≥10%) in patients with wAIHA treated with IMAAVY were peripheral edema, diarrhea and fever.

By targeting the pathogenic IgG autoantibodies that lead to red blood cell destruction in wAIHA, IMAAVY is designed to utilize a differentiated, immunoselective approach, preserving underlying key humoral immune functions in a condition where many patients currently can only rely on unapproved therapies, including corticosteroids and broad immunosuppressants.[2]

"In the first large, placebo-controlled trial of its kind, IMAAVY delivered durable improvements in hemoglobin levels and showed no new safety signals, in a disease with no FDA-approved therapies," said Leonard L. Dragone, M.D., Ph.D., Disease Area Leader, Autoantibody and Rheumatology, Johnson & Johnson. "This immunoselective approach targets the underlying autoantibodies driving disease while preserving key immune functions, which is important

for people living with this disease who frequently suffer with comorbid conditions."

These data support the supplemental Biologics License Application (sBLA) for IMAAVY which has since been granted **U.S. FDA Priority Review**.

Editor's Notes:

a. The dose submitted to the FDA for approval (30 mg/kg IV every four weeks).
b. Durable hemoglobin response, the primary endpoint of the Phase 2/3 ENERGY trial, is defined as hemoglobin concentration ≥10 g/dL and an increase from baseline in hemoglobin ≥2 g/dL for at least 28 days (where criteria was met starting by Week 16 of the double-blind period), without the need of rescue therapy. This endpoint was prespecified within the equal-weight hierarchical testing procedure; the resulting one-sided p-value was considered statistically significant in accordance with the predefined multiplicity control strategy.
c. These data were not a part of the hierarchical testing procedure.
d. Based on mean change from baseline of Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) score at Week 24, a key secondary endpoint, with mean change of 3.51 points over placebo for 30 mg/kg IV treatment group (dose filed with the FDA). This endpoint was prespecified within the hierarchical testing procedure; the resulting one-sided p-value was considered nominal in accordance with the predefined multiplicity control strategy.
e. IMAAVY is not approved for the treatment of warm autoimmune hemolytic anemia.
f. Participants who achieved durable Hgb response were required to initiate corticosteroid (CS) dose tapering. Doses were reduced by 10% of the baseline CS dose every two weeks, provided Hgb levels did not decline by ≥1 g/dL. At Week 24, the mean percent reduction in CS dose was numerically higher in the nipocalimab 30 mg/kg treatment group (15% reduction from baseline dose) compared with placebo (4% reduction from baseline dose). This endpoint was prespecified within the hierarchical testing procedure.
g. Dr. Bruno Fattizzo is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

ABOUT THE ENERGY TRIAL

ENERGY (**NCT04119050**) is a multicenter, randomized, double-blind, placebo-controlled Phase 2/3 study evaluating the efficacy and safety of nipocalimab compared with placebo followed by an open-label extension period, in adults living with warm autoimmune hemolytic anemia (wAIHA). 115 adults were randomized approximately 1:1:1 to receive nipocalimab at two different dose schedules or placebo. Following completion of 24 weeks of double-blind treatment, patients could enter an open-label extension period to receive nipocalimab for 144 weeks with a follow-up period of 6 weeks after last assessment.[3]

ABOUT WARM AUTOIMMUNE HEMOLYTIC ANEMIA (wAIHA)

Warm autoimmune hemolytic anemia (wAIHA) is a rare, life-threatening condition where autoantibodies attach to and destroy red blood cells (RBCs), resulting in anemia.[4] Approximately 1-3 new people per 100,000 are affected by wAIHA per year, and about 1 in 8,000 individuals are living with the condition.[4,5] This condition affects both women and men, and can affect people at any age with incidence increasing over the age of 50.[5,6] Additionally, people with wAIHA are at increased risk of other serious complications such as venous thrombotic events, acute renal failure, and infection.[7]

There are no Food and Drug Administration (FDA)-approved drugs indicated for wAIHA, and treatment typically consists of unapproved corticosteroids, broad immunosuppressants, and B-cell directed therapies.[4] With an unmet need for treatment in wAIHA, novel therapies like nipocalimab are being developed to potentially address this need.[7]

ABOUT IMAAVY (nipocalimab-aahu)

IMAAVY® is an immunoselective treatment designed to target, bind with high affinity, and block the neonatal Fc receptor (FcRn), reducing circulating immunoglobulin G (IgG) antibodies that drive disease while also preserving key immune functions. IMAAVY is currently approved for the treatment of generalized myasthenia gravis (gMG) in adults and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.[8]

Nipocalimab is being investigated across three key segments in the autoantibody space including Rheumatologic diseases, Rare Autoantibody diseases and Maternal Fetal diseases mediated by maternal alloantibodies, in which blockade of IgG binding to FcRn in the placenta is believed to limit transplacental transfer of maternal alloantibodies to the fetus.[3,9,10,11,12,13,14,15,16,17]

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, generalized myasthenia gravis (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 wAIHA in Q2 2026

The legal manufacturer for IMAAVY is Janssen Biotech, Inc.

WHAT IS IMAAVY (nipocalimab-aahu)?

IMAAVY is a prescription medicine used to treat adults and children 12 years of age and older with a disease called generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

It is not known if IMAAVY is safe and effective in children under 12 years of age.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about IMAAVY?

IMAAVY is a prescription medicine that may cause serious side effects, including:

- Infections are a common side effect of IMAAVY that can be serious. Receiving IMAAVY may increase your risk of infection. Tell your healthcare provider right away if you have any of the following infection symptoms:

- fever
- chills
- shivering
- cough
- sore throat
- fever blisters
- burning when you urinate

- Allergic (hypersensitivity) reactions may happen during or up to a few weeks after your IMAAVY infusion. Get emergency medical help right away if you get any of these symptoms during or after your IMAAVY infusion:

- a swollen face, lips, mouth, tongue, or throat
- difficulty swallowing or breathing
- itchy rash (hives)
- chest pain or tightness

- Infusion-related reactions are possible. Tell your healthcare provider right away if you get any of these symptoms during or a few days after your IMAAVY infusion:

- headache
- rash
- nausea
- fatigue
- dizziness
- chills
- flu-like symptoms
- redness of skin

Do not receive IMAAVY if you have a severe allergic reaction to nipocalimab-aahu or any of the ingredients in IMAAVY. Reactions have included angioedema and anaphylaxis.

Before using IMAAVY, tell your healthcare provider about all of your medical conditions, including if you:

- ever had an allergic reaction to IMAAVY.
- have or had any recent infections or symptoms of infection.
- have recently received or are scheduled to receive an immunization (vaccine). People who take IMAAVY should not receive live vaccines.
- are pregnant, plan to become pregnant, or are breastfeeding. It is not known whether IMAAVY will harm your baby.

  Pregnancy Safety Study. There is a pregnancy safety study for IMAAVY if IMAAVY is given during pregnancy or you become pregnant while receiving IMAAVY. Your healthcare provider should report IMAAVY exposure by contacting Janssen at 1-800-526-7736 or **www.IMAAVY.com**.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of IMAAVY?
IMAAVY may cause serious side effects. See "What is the most important information I should know about IMAAVY?"

The most common side effects of IMAAVY include: respiratory tract infection, peripheral edema (swelling in your hands, ankles, or feet), and muscle spasms.

These are not all the possible side effects of IMAAVY. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch**, or call **1-800-FDA-1088**.

Please see the full **Prescribing Information** and **Medication Guide** for IMAAVY and discuss any questions you have with your doctor.

Dosage Form and Strengths: IMAAVY is supplied as a 300 mg/1.62 mL and a 1,200 mg/6.5 mL (185 mg/mL) single-dose vial per carton for intravenous injection.

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 IMAAVY. 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**, **www.investor.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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