Johnson&Johnson

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Johnson & Johnson seeks FDA approval of IMAAVY® (nipocalimab-aahu) as the first-ever FDA-approved treatment for warm autoimmune hemolytic anemia (wAIHA)

Data from the pivotal ENERGY trial showed IMAAVY® produced a rapid and durable hemoglobin response[a] in wAIHA

Currently no FDA-approved therapies are available for wAIHA, a rare, heterogeneous, life-threatening disease in which pathogenic immunoglobulin (IgG) autoantibodies attach to and destroy red blood cells, leading to debilitating anemia

SPRING HOUSE, Pa., (February 24, 2026) – Johnson & Johnson (NYSE: JNJ) today announced the submission of a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA), seeking approval of IMAAVY® (nipocalimab-aahu) as the first-ever treatment for patients with warm autoimmune hemolytic anemia (wAIHA).[b] This rare and serious autoantibody disease affects approximately 1 in 8,000 in the United States and currently has no approved treatments despite substantial unmet need.[1] The condition is associated with significant morbidity and mortality, with those living with the disease found to experience a 20-30% higher risk of death.[2]

“People living with warm autoimmune hemolytic anemia face a serious, life-threatening disease with no approved treatment options and a high risk of complications, including profound chronic fatigue, transfusion dependence, and organ failure” said David M Lee, M.D., Ph.D., Global Immunology Therapeutic Area Head, Johnson & Johnson. “The submission of this sBLA represents an important milestone for the wAIHA community and underscores our commitment to advancing targeted, immunoselective therapies that can deliver meaningful, rapid improvement for these patients.”

wAIHA occurs when harmful immunoglobulin G (IgG) autoantibodies attach to and destroy red blood cells – leading to anemia.[3] IMAAVY® is designed to selectively block the neonatal Fc receptor (FcRn), a key regulator of IgG recycling.[4] By reducing circulating IgG, including autoantibodies, IMAAVY® targets the underlying cause of disease while preserving critical immune functions, including some humoral B-cell responses to new infections.

The sBLA submission is supported by the Phase 2/3 ENERGY multicenter, randomized, double-blind, placebo-controlled study (NCT04119050) evaluating IMAAVY® in adults living with wAIHA. The data showed that more patients treated with nipocalimab achieved the stringent primary endpoint of a durable hemoglobin response compared with placebo. A durable response was defined as achieving a hemoglobin level above 10 g/dL and an increase of at least 2 g/dL for at least 28 days, without the need for rescue therapy.[5]

In addition to a rapid and durable improvement in hemoglobin, more patients treated with IMAAVY® experienced rapid and sustained improvement in fatigue as assessed by FACIT-Fatigue, an outcome of significant importance to people living with wAIHA.[5]

“The ENERGY study demonstrated clinically meaningful results in adults living with warm autoimmune hemolytic anemia,” said Bruno Fattizzo, M.D., Assistant Professor at the Department of Oncology and Hematology-Oncology, Università degli Studi di Milano[c]. “These results provide a strong rationale for the potential of IMAAVY to rapidly improve fatigue and provide durable hemoglobin response while maintaining favorable tolerability.”

IMAAVY® was generally well tolerated in ENERGY, with no new safety signals identified and a safety profile consistent with the IMAAVY® label.[5,6] IMAAVY® was approved in the United States in April 2025 for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are acetylcholine receptor (AChR) or muscle-specific kinase (MuSK) antibody positive.[6]

The full results of the ENERGY trial are forthcoming.

Editor’s notes:

a. Durable hemoglobin response = hemoglobin concentration ≥10 g/dL *and* an increase from baseline in Hgb ≥2 g/dL for at least 28 days
b. IMAAVY® is not approved in wAIHA
c. Dr. Fattizzo has served as a consultant to J&J; he has not been paid 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 wAIHA.[5]

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. 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.[1,7] This condition affects both women and men, and can affect people at any age with incidence increasing over the age of 50.[8,9] Additionally, people with wAIHA are at increased risk of other serious complications such as venous thrombotic events, acute renal failure, and infection.[10]

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.[7] With an unmet need for treatment in wAIHA, novel therapies like nipocalimab that can deliver meaningful improvement to patients is critical.[9]

ABOUT IMAAVY® (nipocalimab-aahu)
IMAAVY® is an 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. IMAAVY® is currently approved for the treatment of gMG in adults and pediatric patients 12 years of age and older who are AChR or MuSK antibody positive.[6]

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.[11,12,13,14,15,16,17,18,19,20]

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, fetal and neonatal alloimmune thrombocytopenia) FNAIT in March 2024 and 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 and FNAIT in April 2025

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.

Learn more at https://www.jnj.com/ or at www.innovativemedicine.jnj.com.

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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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