Johnson&Johnson

NEWS RELEASE

FDA approves IMAAVY® (nipocalimab-aahu) as first-ever treatment for warm autoimmune hemolytic anemia (wAIHA), representing a landmark advancement for patients

2026-08-24

- IMAAVY is an immunoselective FcRn blocker designed to target and reduce pathogenic immunoglobulin G (IgG) autoantibodies while also preserving B-cell function
- Warm autoimmune hemolytic anemia is a rare, life-threatening disease in which autoantibodies cause the destruction of red blood cells, leading to severe anemia and debilitating fatigue
- The approval is based on the pivotal Phase 2/3 study which demonstrated durable hemoglobin response[a]
- A mean increase in hemoglobin of 1 g/dL at Week 1[b] and improvement in FACIT-Fatigue[c] score at Week 24 were observed in IMAAVY-treated patients[d]

SPRING HOUSE, Pa., Aug. 24, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced the U.S. Food and Drug Administration (FDA) approval of IMAAVY® (nipocalimab-aahu) for the treatment of warm autoimmune hemolytic anemia (wAIHA) – a rare, life-threatening autoantibody disease – in adults and pediatric patients 12 years of age and older currently or previously treated with corticosteroids. The approval, which follows **FDA Priority Review**, marks the first time a therapy was proven safe and effective specifically for the treatment of wAIHA.[1]

"Living with wAIHA often means relentless fatigue and the constant uncertainty of not knowing what tomorrow will bring," said Karen Jones, President and Executive Director, wAIHA Warriors.[e] "Patients may cycle through periods where they start to feel like themselves again — and then their hemoglobin drops, the exhaustion returns, and they're back to square one. For the first time, our community has a treatment specifically for our disease."

Addressing serious unmet need in wAIHA

In wAIHA, pathogenic immunoglobulin G (IgG) autoantibodies attach to and destroy red blood cells, causing severe anemia, profound fatigue, and a significantly increased risk of morbidity and mortality.[2] Previously, available treatment options only included corticosteroids and immunosuppressants — therapies that suppress the entire immune system without specifically targeting the IgG autoantibodies driving the disease.[3]

"The Phase 2/3 ENERGY study demonstrates that targeting pathogenic IgG can meaningfully change the treatment paradigm for wAIHA," said David Kuter, M.D., D.Phil., Distinguished Physician, Massachusetts General Hospital and Professor of Medicine at Harvard Medical School.[f] "More patients treated with IMAAVY achieved a durable hemoglobin response compared with placebo — meaning their red blood cell levels went up and stayed up. For patients, this approval means that they now have a therapy with a proven safety profile that targets the disease-driving autoantibodies in wAIHA."

Clinical evidence summary of IMAAVY in wAIHA

The primary endpoint of the Phase 2/3 ENERGY study was durable hemoglobin (Hgb) response,[a] a stringent endpoint definition that reflects meaningful increases in Hgb levels over time.[4,5] The randomized, placebo-controlled trial demonstrated approximately three times as many patients receiving the approved dose of IMAAVY[g] achieved durable Hgb levels versus placebo by 24 weeks.[5,h] Overall patients in this treatment group showed a mean increase in Hgb of 1g/dL at Week 1.[5,b] In addition, IMAAVY was associated with a 3.5-point higher mean FACIT-Fatigue[c] score versus placebo at Week 24, with higher scores defined as less fatigue.[5,d] In the ENERGY study IMAAVY demonstrated a safety profile consistent with the established safety profile of IMAAVY in generalized myasthenia gravis (gMG).[4] The most common adverse reactions (≥10%) in patients with wAIHA treated with IMAAVY were peripheral edema, diarrhea, and fever.[5]

The full results of the ENERGY study were presented at the European Hematology Association 2026 meeting in June 2026.

Building on a proven approach to autoantibody-driven disease

"Today's announcement marks the second approval for IMAAVY and is an extraordinary milestone for people living with warm autoimmune hemolytic anemia, an underserved community that has waited far too long for an FDA-approved treatment," said David M. Lee, M.D., Ph.D., Global Immunology Therapeutic Area Head, Johnson & Johnson. "As the first therapy approved for wAIHA, IMAAVY has the potential to redefine the management of wAIHA, particularly for those with uncontrolled disease. This milestone reinforces our motivation to continue pursuing advanced therapies for people living with allo- and autoantibody diseases like wAIHA."

IMAAVY was approved in the United States in April 2025 for the treatment of gMG in adult and pediatric patients 12 years of age and older who are acetylcholine receptor (AChR) or muscle-specific kinase (MuSK) antibody positive.[5]

Johnson & Johnson is committed to helping patients access our treatments. Once a decision has been made to prescribe IMAAVY, the IMAAVY withMe patient support program provides personalized support including educational resources, a dedicated Nurse Navigator,[i] and cost support options – regardless of insurance type.

Editor's Notes:

a. Durable hemoglobin (Hgb) response, the primary endpoint of the Phase 2/3 ENERGY trial, is defined as Hgb concentration ≥10 g/dL and an increase from baseline in Hgb ≥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[5]

b. A mean increase of 1 g/dL in Hgb was observed at Week 1. Among the responders, the median time to first Hgb response was 4.1 (range: 1 to 12) weeks in patients treated with IMAAVY 30 mg/kg every 4 weeks, compared to 12.1 (range: 4 to 16) weeks in the placebo group. Results are considered descriptive based on the study's pre-specified statistical analysis plan[6]

c. Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue)

d. Mean change from baseline of FACIT-Fatigue score at Week 24, a key secondary endpoint, with mean difference of 3.51 (95% CI: 0.64; 6.39) points in the IMAAVY 30 mg/kg IV treatment group compared to placebo.[5] Results are considered descriptive based on the study's pre-specified statistical analysis plan[6]

e. Karen Jones has not been compensated for any media work

f. Dr. Kuter has served as a consultant to J&J; he has not been paid for any media work

g. 30 mg/kg q4w is the approved dose

h. Durable Hgb response, as defined in Editor's note "a," was achieved with statistical significance in the approved 30 mg/kg IV q4w treatment group[5]

i . Nurse Navigators do not provide medical advice

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).[7] 115 adults were randomized approximately 1:1:1 to receive nipocalimab at two different dose schedules or placebo.[7] 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.[7]

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.[8] 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.[8,9] This condition affects both women and men, and can affect people at any age with incidence increasing over the age of 50.[9,10] Additionally, people with wAIHA are at increased risk of other serious complications such as venous thrombotic events, acute renal failure, and infection.[11]

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 B-cell function based on in vitro and/or in vivo studies.[12,13] 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.[5] IMAAVY is also approved for the treatment of warm autoimmune hemolytic anemia (wAIHA) in adult and pediatric patients 12 years of age and older currently or previously treated with corticosteroids.[5]

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.[14,15,16,17,18,19,20,21]

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 gMG in Q4 2024 and wAIHA in Q2 2026

The legal manufacturer for IMAAVY is Janssen Biotech, Inc.

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. IMAAVY may increase your risk of infections, including serious infections. If you have an infection, your healthcare provider will treat your infection or delay your infusion until your infection is gone. 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
- trouble breathing

- Allergic (hypersensitivity) reactions can happen during or up to a few weeks after your IMAAVY infusion. Tell your healthcare provider and 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
- trouble swallowing or breathing
- hives
- itchy rash
- chest pain or tightness

- Infusion-related reactions. Tell your healthcare provider right away if you get any of these symptoms during or within 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 history of a severe allergic reaction to nipocalimab-aahu or any of the ingredients in IMAAVY. Reactions have included angioedema and anaphylaxis. Refer to the Patient Information section of the Prescribing Information for a complete list of ingredients in IMAAVY.

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

- have had an allergic reaction to IMAAVY.
- have or had any recent infections or symptoms of infection.
- have or had shingles (herpes zoster) or mono (mononucleosis caused by Epstein-Barr virus).
- have recently received or are scheduled to receive an immunization (vaccine). People who take IMAAVY should not receive live vaccines.
- are pregnant or plan to become pregnant. It is not known if IMAAVY will harm your unborn 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.
- are breastfeeding or plan to breastfeed. IMAAVY can pass into your breast milk. It is not known if IMAAVY will harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with IMAAVY.

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 in people with gMG treated with IMAAVY include: respiratory tract infection, peripheral edema (swelling in your hands, ankles, or feet), and muscle spasms.

The most common side effects in people with wAIHA treated with IMAAVY include: peripheral edema (swelling in your hands, ankles, or feet), diarrhea, and pyrexia (fever).

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 **Patient Information** 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.**

Follow us at **@JNJInnovMed**.

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 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.

REFERENCES

[1] Johnson & Johnson. Press Release: FDA grants Priority Review for IMAAVY® (nipocalimab-aahu) as the potential first approved treatment for people living with warm autoimmune hemolytic anemia (wAIHA). Available at: **https://www.jnj.com/media-center/press-releases/fda-grants-priority-review-for-imaavy-nipocalimab-aahu-as-the-potential-first-approved-treatment-for-people-living-with-warm-autoimmune-hemolytic-anemia-waiha**. Last accessed: April 2026.

[2] Rarediseases.org. Warm Autoimmune Hemolytic Anemia. Available at **https://rarediseases.org/rare-diseases/warm-autoimmune-hemolytic-anemia/**. Last accessed: February 2025.

[3] Sudulagunta SR, et al. Warm Autoimmune Hemolytic Anemia: Clinical Profile and Management. J Hematol. 2017 Mar; 6(1): 12–20. Published online 2017 Mar 21. doi: 10.14740/jh303w.

[4] Fattizzo B, Murakhovskaya I, Ueda.Y, Schlichting D, Sweet K, Zelasky M, Craig J, Liva S, Leu J, Ling L, Pease S, Anakor A, Shu C, Nipocalimab for warm autoimmune hemolytic anemia: results from the Phase 2/3 randomized, double-blind ENERGY study, Presented at EHA 2026 Congress, Available at: **https://library.ehaweb.org/eha/2026/eha-2026/4206854/bruno.fattizzo.nipocalimab.for.warm.autoimmune.hemolytic.anemia.results.from.html**

[5] IMAAVY® U.S. Prescribing Information.

[6] J&J. Data on File.

[7] ClinicalTrials.gov Identifier: NCT04119050. Available at: **https://www.clinicaltrials.gov/study/NCT04119050**

[8] National Organization for Rare Disorders, Warm autoimmune Hemolytic Anemia. Available at: **https://rarediseases.org/rare-diseases/warm-autoimmune-hemolytic-anemia/**. Last accessed: February 2025.

[9] Tranekær S, Hansen DL, Frederiksen H. Epidemiology of Secondary Warm Autoimmune Haemolytic Anaemia-A Systematic Review and Meta-Analysis. J Clin Med. 2021 Mar 17;10(6):1244. doi: 10.3390/jcm10061244. PMID: 33802848; PMCID: PMC8002719.

[10] Cherif, H., Cai, Q., Crivera, C., Leon, A., Rahman, I., Leval, A., Noel, W. and Kjellander, C. (2024), Overall Survival and Treatment Patterns Among Patients With Warm Autoimmune Hemolytic Anemia in Sweden: A Nationwide Population-based Study. Eur J Haematol. **https://doi.org/10.1111/ejh.14311**.

[11] Fattizzo B, Barcellini W. New Therapies for the Treatment of Warm Autoimmune Hemolytic Anemia. Transfusion Medical Reviews, Vol. 36, Issue 4. October 2022 **https://doi.org/10.1016/j.tmrv.2022.08.001**.

[12] Ling LE., et al. M281, an anti-fcrn antibody: Pharmacodynamics, pharmacokinetics, and safety across the full range of IGG reduction in a first-in-human study. Clinical Pharmacology & Therapeutics., 2018;105;4:1031–1039. Available at: **https://doi.org/10.1002/cpt.1276**.

[13] Cossu M et al. A randomized, open-label study on the effect of nipocalimab vaccine response in healthy participants. Presentation at American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting. October 2024.

[14] ClinicalTrials.gov Identifier: NCT04951622. Available at: **https://clinicaltrials.gov/ct2/show/NCT04951622**. Last accessed: August 2026.

[15] ClinicalTrials.gov Identifier: NCT05327114. Available at: **https://www.clinicaltrials.gov/study/NCT05327114**. Last accessed: August 2026.

[16] ClinicalTrials.gov Identifier: NCT04119050. Available at: **https://clinicaltrials.gov/study/NCT04119050**. Last accessed: August 2026.

[17] ClinicalTrials.gov Identifier: NCT05379634. Available at: **https://clinicaltrials.gov/study/NCT05379634**. Last accessed: August 2026.

[18] ClinicalTrials.gov Identifier: NCT05912517. Available at: **https://www.clinicaltrials.gov/study/NCT05912517**. Last accessed: August 2026.

[19] ClinicalTrials.gov Identifier: NCT06533098 Available at: **https://clinicaltrials.gov/study/NCT06533098**. Last accessed: August 2026.

[20] ClinicalTrials.gov Identifier: NCT06741969 Available at: **https://clinicaltrials.gov/study/NCT06741969** Last accessed: August 2026.

[21] ClinicalTrials.gov Identifier: NCT07438496 Available at: **https://clinicaltrials.gov/study/NCT07438496** Last accessed: August 2026.

View original content to download multimedia:**https://www.prnewswire.com/news-releases/fda-approves-imaavy-nipocalimab-aahu-as-first-ever-treatment-for-warm-autoimmune-hemolytic-anemia-waiha-representing-a-landmark-advancement-for-patients-302858778.html**

SOURCE Johnson & Johnson