Johnson&Johnson

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For immediate release

New real-world data elevating patient perspectives highlight the need for scientific advancement in maternal fetal immunology at ISUOG 2025

Patients share experiences of confusion, fear and fragmented care in managing pregnancies at risk for hemolytic disease of the fetus and newborn (HDFN) or fetal neonatal alloimmune thrombocytopenia (FNAIT) under current standard of care

These patient perspectives highlight the gap that remains for treatments that address the significant unmet need in life-threatening immune-mediated conditions during pregnancy

The Phase 3 AZALEA, FREESIA-1 and FREESIA-3 clinical studies of nipocalimab, an investigational FcRn blocker, are enrolling pregnant individuals at risk for severe HDFN and FNAIT

SPRING HOUSE, Pa., (September 3, 2025) – Johnson & Johnson (NYSE: JNJ) announced today that six abstracts, including an oral poster presentation, will be shared at the 35th International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) World Congress from September 14 – 17 in Cancún, Mexico, spotlighting persistent unmet needs in maternal fetal immunology. Alloantibody diseases, such as HDFN and FNAIT, develop when maternal antibodies, or alloantibodies, produced by a pregnant person's immune system, cross the placenta. In the case of HDFN, these alloantibodies attack the fetal red blood cells, while in FNAIT they attack the fetal or newborn platelets.[1,2] These conditions can have severe consequences for both the mother and the fetus. HDFN can lead to fetal anemia, while FNAIT can lead to thrombocytopenia and the risk of bleeding, all of which may result in lifelong implications for the fetus.[1,2]

"For families navigating pregnancies affected by HDFN and FNAIT, the experience is often filled with fear and uncertainty and presents an additional burden of self-advocacy. Earlier diagnosis, greater awareness of the diseases and access to innovative therapies have the potential to transform outcomes for thousands of parents and newborns," said Bethany Weathersby, Founder and Executive Director, The Allo Hope Foundation. "The new patient insights presented at ISUOG show patients feel the intense need to advocate for themselves in the face of fragmented care and uncertainty following diagnosis, reinforcing a critical need to transform care pathways so no patient has to navigate this journey feeling unsupported in the future."

New real-world studies reveal lived realities of pregnancies affected by HDFN and FNAIT, exploring the treatment patterns and outcomes of intrauterine transfusions (IUTs), the standard of care used to manage HDFN, as well as the complex diagnosis journey patients experience with FNAIT.[3,4]

"Despite the severity of these conditions, there are no approved therapeutics that are effective and have a proven safety profile to help address the serious health consequences of HDFN and FNAIT," said Leonard L. Dragone, M.D., Ph.D., Disease Area Leader, Rheumatology and Autoantibody, Johnson & Johnson Innovative Medicine. "These new patient insights presented at ISUOG confirm the acute need for earlier diagnosis and intervention to deliver the care these patients deserve."

Johnson & Johnson received U.S. FDA Breakthrough designation for nipocalimab in severe HDFN in February 2024, and Fast Track designations for nipocalimab in severe HDFN and FNAIT in July 2019 and March 2024, respectively.[5,6] The Phase 3 AZALEA trial is currently enrolling pregnant individuals who are at risk of severe HDFN.[7] The Phase 3 FREESIA-1 and FREESIA-3 trials are currently enrolling pregnant individuals who are at risk of an FNAIT pregnancy.[8,9]

The full list of accepted Johnson & Johnson abstracts is below.

Data presentation highlights: ISUOG – September 14-17

Presenter/Presentation Time (CST) Poster Number	Abstract Name
Oral Session	
OP11.04 **Date:** September 17 **Presentation Time:** 3:15 PM to 3:55 PM	**Pregnancy complications: before and after pregnancy:** All-cause inpatient healthcare resource utilization and direct costs in children affected by Hemolytic Disease of the Fetus and Newborn in Sweden
Poster Session	
EP17.58	Lived Experiences with Pregnancies Affected by Severe Hemolytic Disease of the Fetus and Newborn (HDFN): An Interview Study
EP10.11	Outcomes of intrauterine transfusion for the treatment of Hemolytic Disease of the Fetus and Newborn
EP17.10	Clinical outcomes and treatment patterns in Hemolytic Disease of the Fetus and Newborn: evidence from United States claims data
EP16.73	Qualitative patient experiences of hemolytic disease of the fetus and newborn (HDFN): psychosocial impacts reported during an ongoing patient council
EP16.32	Qualitative patient experiences of fetal and neonatal alloimmune thrombocytopenia (FNAIT): diagnostic and treatment challenges

ABOUT HEMOLYTIC DISEASE OF THE FETUS AND NEWBORN (HDFN)

Hemolytic disease of the fetus and newborn (HDFN) is a rare disease in which the maternal alloantibodies cross the placenta during pregnancy and attack fetal red blood cells causing fetal anemia.[1,10] If not treated in a timely manner by a knowledgeable clinician, the anemic fetus may develop severe fetal hydrops with life-threatening consequences, such as heart failure and/or death.[11] After birth, infants may be affected by neonatal hyperbilirubinemia and persistent anemia requiring transfusions. In general, the severity of HDFN increases with each subsequent pregnancy.[12] Currently no non-surgical interventions are approved for pregnancies at high risk of severe HDFN in the U.S. Pregnancies affected by severe HDFN may necessitate repeated intrauterine transfusions (IUTs).[13] According to guidelines published by the British Society of Hematology, IUTs are invasive procedures with a risk of fetal death of 1–3% per procedure and are only undertaken in specialized fetal medicine units with the requisite interventional skills and expertise.[10] The most difficult to treat cases of HDFN are those that develop before 24 weeks gestational age, defined here as early-onset, due to high rates of IUT-related complications associated with mortality.[14] It is estimated that up to 80 out of every 100,000 pregnancies are affected by HDFN.[15]

ABOUT FETAL NEONATAL ALLOIMMUNE THROMBOCYTOPENIA (FNAIT)

Fetal neonatal alloimmune thrombocytopenia (FNAIT) is a rare and potentially life-threatening alloimmune condition in which a pregnant person's immune system develops antibodies against fetal or newborn platelet antigens, leading to thrombocytopenia (low platelet counts in the fetus or newborn).[1] FNAIT can result in severe bleeding complications for a fetus or newborn and is characterized by organ bleeding in the gastrointestinal tract, lungs, or eyes, and may result in lifelong disability or death.[1] If a severe bleed occurs in the brain, termed intracranial hemorrhage (ICH), death or life-long neurologic effects could occur.[1] ICH occurs in up to 26% of untreated pregnancies with FNAIT. There are no approved therapies for FNAIT management and while conventional interventions like intravenous immunoglobulin (IVIG) can increase the chance of fetal and infant survival, there remains an immense need for approved treatments with demonstrated safety profiles.[16] FNAIT is not routinely screened for during pregnancy and firstborn children with FNAIT are often only diagnosed postnatally.[1] It is estimated 1 in 1000 pregnancies are affected by FNAIT.[1,17]

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.[18] 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.[7,19,20,21,22,23,24,25,26] Blockade of IgG binding to FcRn in the placenta is also believed to limit transplacental transfer of maternal alloantibodies to the fetus.[27,28]

The U.S. FDA and EMA have granted several key designations to nipocalimab in the Maternal Fetal segment:

- U.S. FDA Fast Track designation in hemolytic disease of the fetus and newborn (HDFN) and fetal neonatal alloimmune thrombocytopenia (FNAIT) in March 2024
- U.S. FDA Orphan drug status for FNAIT in December 2023
- U.S. FDA Breakthrough Therapy designation for HDFN in February 2024 EU EMA Orphan medicinal product designation for HDFN in October 2019 and FNAIT in April 2025

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 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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