Johnson&Johnson

Media contact:
Bridget Kimmel
Mobile: +1 215 688-6033
bkimmel@its.jnj.com

Investor contact:
Raychel Kruper
investor-relations@its.jnj.com

Johnson & Johnson spotlights nipocalimab at FMF Congress 2024 – the first and only FcRn blocker to be studied in maternal fetal diseases

The Phase 3 AZALEA and Phase 3 FREESIA clinical studies are enrolling pregnant individuals who are at risk for severe HDFN and FNAIT

These rare and potentially life-threatening alloantibody diseases affecting pregnant individuals and their fetus or newborn currently have no approved treatments

LISBON (June 24, 2024) – Johnson & Johnson (NYSE: JNJ) today announced that seven presentations featuring the Company's research in maternal-fetal immunology will be shared at the Fetal Medicine Foundation World Congress 2024.

Data presentations will highlight the Company's continued evaluation of nipocalimab for the potential treatment of pregnant individuals with hemolytic disease of the fetus and newborn (HDFN) and fetal and neonatal alloimmune thrombocytopenia (FNAIT). When completed, this research will further define the unmet needs in these rare conditions caused by placental transfer of alloantibodies which pose significant risk to the fetus or newborn.

"We are deeply committed to research with a goal of providing safe treatment options that address the underlying causes and serious health consequences associated with HDFN and FNAIT – two diseases for which there are no approved therapeutic options," said Katie Abouzahr, M.D., Vice President, Autoantibody Portfolio and Maternal Fetal Immunology Disease Area Leader, Johnson & Johnson. "There is an ongoing need for continued innovation in maternal fetal immunology with the aim of delivering safe and effective therapies for these diseases."

Data presentation highlights: Showcasing research in HDFN and FNAIT

Abstract Name
Hemolytic disease of the fetus and newborn
Management and outcomes in hemolytic disease of the fetus and newborn: a systematic literature review
Nipocalimab pharmacodynamics in a Phase 2 study in pregnancies at risk of early-onset severe hemolytic disease of the fetus and newborn (HDFN)
Nipocalimab pharmacokinetic/pharmacodynamic and exposure-response modeling in pregnancies at risk for early-onset severe (EOS) HDFN
Fetal and neonatal alloimmune thrombocytopenia
Design of a Phase 3, multicenter, randomized, placebo-controlled, double-blind study of nipocalimab in pregnancies at risk for fetal and neonatal alloimmune thrombocytopenia (FREESIA-1)
Allele frequencies for the most common antigens that cause alloimmunization in FNAIT, HPA-1a and HPA-5b, are similar across diverse populations
Both conditions
SF-36v2[a] for assessment in HDFN or FNAIT-affected pregnancies - results of a landscape assessment and clinician and patient interviews in the US
Mixed methods research to understand disease burden and unmet need in HDFN and FNAIT

Ongoing commitment to maternal-fetal immunology

- Johnson & Johnson is committed to working with the maternal-fetal immunology community, patients and families to advance research to help address diseases that affect pregnant populations
    - J&J Innovative Medicine will be hosting a booth with more information on its efforts across the maternal-fetal space.

Enrollment in a Johnson & Johnson maternal-fetal clinical trial

- The AZALEA pivotal Phase 3 trial is currently enrolling pregnant individuals who are at risk of a severe HDFN pregnancy
- The FREESIA pivotal Phase 3 trial is currently enrolling patients who are at risk of an FNAIT pregnancy

Editor's Note:

a. SF-36v2 is a short-form health survey that measures each of the following eight health domains: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health. These factors are used to assess the quality of life and functional health and well-being of patients across a variety of health conditions.

ABOUT HDFN

Hemolytic disease of the fetus and newborn (HDFN) is a rare disease (and in its severe form, ultra rare) that arises in pregnancies with maternal-fetal incompatibility in certain red blood cell types.[1] Alloantibodies produced by the maternal immune system against fetal red blood cells cross the placenta during pregnancy and attack fetal red blood cells causing fetal anemia or persist after birth in the neonate to cause neonatal hyperbilirubinemia and anemia.[2] The symptoms of HDFN can range from mild jaundice, to neurotoxic hyperbilirubinemia in the newborn, to life-threatening fetal anemia requiring invasive intervention.[3] The potential for in utero onset at an increasingly earlier GA with increasing risk of severe outcomes may occur with each incompatible pregnancy due to pregnancy-related alloimmunization.[4] Currently there are no non-surgical interventions approved for pregnancies at high risk for severe HDFN.[5] Pregnancies affected by severe HDFN may necessitate repeated intrauterine transfusions (IUTs), which are invasive, technically complex surgical procedures performed by specialists at specialized medical centers, and these procedures are associated with an increased rate of fetal mortality and premature birth.[6,7,8] The most difficult to treat cases of HDFN are early onset severe HDFN (EOS-HDFN) that develops at ≤24 weeks gestational age (GA) and results in significant fetal/neonatal morbidity and mortality. According to the *American Journal of Obstetrics and Gynecology*, in the U.S., it is estimated that up to 80 of every 100,000 pregnancies are affected by HDFN each year.[9]

ABOUT FNAIT

Fetal neonatal alloimmune thrombocytopenia (FNAIT) is a rare and potentially life-threatening alloimmune condition in which a pregnant person's immune system develops alloantibodies against fetal or newborn platelet antigens, leading to thrombocytopenia (low platelet counts) in the fetus or newborn.[10]

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.[10] If a severe bleed occurs in the brain, termed intracranial hemorrhage (ICH), death or life-long neurologic effects may occur.[10] ICH occurs in up to 26 percent of untreated pregnancies with FNAIT.[11]

It has an estimated incidence rate of 1 in 1000 pregnancies.[10,12] There are no approved therapies for the treatment of FNAIT. Because FNAIT is not routinely screened for during pregnancy, the diagnosis of an affected FNAIT pregnancy often occurs postnatally.[10]

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.[13,14,15,16,17,18,19,20,21] Blockade of IgG binding to FcRn in the placenta is also believed to prevent transplacental transfer of maternal alloantibodies to the fetus.[22,23]

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 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 by the FDA in February 2024
- Orphan medicinal product designation for HDFN by the EMA 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.

Janssen Research & Development, LLC and Janssen Biotech, Inc. 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 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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