Johnson&Johnson

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

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

Johnson & Johnson highlights innovation in hemolytic disease of the fetus and newborn (HDFN) at the Society for Maternal-Fetal Medicine's (SMFM) 2024 Pregnancy Meeting

Presentations include additional analyses of nipocalimab data from pregnancies at risk for early-onset severe HDFN; Nipocalimab is the only anti-FcRn being studied in this rare and potentially life-threatening two-person disease for which there are no approved non-surgical therapies

Spring House, Pa. (February 9, 2024) – Johnson & Johnson announced today that three presentations featuring the Company's innovations in maternal-fetal medicine will be showcased at the Society for Maternal-Fetal Medicine's (SMFM) 2024 Pregnancy Meeting. Data presentations will highlight the Company's continued evaluation of nipocalimab for the treatment of pregnant individuals at high risk for early-onset severe (EOS) hemolytic disease of the fetus and newborn (HDFN) as well as further underscoring the unmet needs in this rare condition which occurs when the blood types of a pregnant individual and the fetus are incompatible, potentially causing life-threatening anemia in the fetus or infant.[1,2]

"Our presence at this year's Pregnancy Meeting demonstrates our commitment to innovating on behalf of patients who need proven, safe, non-surgical solutions to help address the serious health consequences of HDFN, a rare disease for which no therapeutics are currently approved," said Katie Abouzahr, M.D., Vice President, Autoantibody Portfolio and Maternal Fetal Immunology Disease Area Leader, Johnson & Johnson. "Through our continued focus on understanding the patient journey, developing treatment strategies, and determining how to identify pregnancies at risk for HDFN more quickly, we hope to transform the standard of care for this disease that not only affects the fetus and newborn, but also impacts the pregnant woman and their family."

Data presentation highlights: Accelerating innovation in HDFN

- Data will be presented from the UNITY study that informed the appropriate dose regimen for the AZALEA pivotal Phase 3 trial in pregnant individuals at risk for severe HDFN, which is recruiting patients (Poster #232).
- Data will be presented from an evaluation of fetal and neonatal drug exposure following nipocalimab treatment in pregnant individuals at risk of EOS HDFN during a poster session (Poster #503).
- A real-world evidence (RWE) study will be presented that aims to identify HDFN patients more accurately and completely using novel combinations of medical indicators (structured and unstructured data) (Poster #362).

Ongoing commitment to maternal-fetal medicine

- Our presence at the 2024 Pregnancy Meeting demonstrates the Company's ongoing commitment to working with the maternal-fetal medicine community, patients and their families to advance groundbreaking research and treatment options for unmet needs in underserved pregnant populations.
    - J&J will sponsor a Diversity, Equity and Inclusion networking reception to take place on Monday, 2/12, from 7-8 p.m. EST.
    - An industry lunch symposium titled *Maternal Fetal Immunology – A New Frontier* will feature presenter Kenneth Moise, Jr., MD, Director of the Comprehensive Fetal Care Center at Dell Childrens' Medical Center and a separate patient panel following Dr. Moise's presentation, on Tuesday, 2/13, from 12-1 p.m. EST.
    - J&J will be hosting a booth with more information on its efforts across the maternal-fetal space (#512).
- The AZALEA pivotal Phase 3 trial is currently enrolling pregnant individuals who have a history of severe HDFN in a prior pregnancy(ies).

About HDFN

Hemolytic disease of the fetus and newborn (HDFN) is a rare disease (and in its severe form, even rarer) 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.[3] The symptoms of HDFN can range from mild jaundice, to neurotoxic hyperbilirubinema in the neonate, to life-threatening fetal anemia requiring invasive intervention.[4] The potential for in utero onset at increasingly earlier gestational age with increasing risk of severe outcomes may occur with each incompatible pregnancy due to pregnancy-related alloimmunization.[5] Currently no non-surgical interventions are approved for pregnancies at high risk of early-onset severe (EOS) HDFN in the U.S. Pregnancies affected by severe HDFN may necessitate repeated intrauterine transfusions (IUTs).[6] IUTs are invasive, technically complex

surgical procedures performed by specialists at specialized medical centers, and these procedures may be associated with an increased rate of fetal mortality and premature birth.[7,8] The most difficult to treat cases of HDFN are those that develop before 24 weeks gestational age, defined here as EOS, due to high rates of IUT-related complications associated with mortality.[9] 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.[2]

About Nipocalimab

Nipocalimab is an investigational, high-affinity, fully human, aglycosylated, effectorless, monoclonal antibody that aims to selectively block FcRn to reduce levels of circulating immunoglobulin G (IgG) antibodies, including autoantibodies and alloantibodies that underlie multiple conditions.[10] Nipocalimab is the only anti-FcRn being studied across three key segments in the autoantibody space: maternal-fetal diseases mediated by maternal alloantibodies (e.g., HDFN); rare autoantibody diseases (e.g., generalized myasthenia gravis in adults and children, chronic inflammatory demyelinating polyneuropathy, warm autoimmune hemolytic anemia, and idiopathic inflammatory myopathies); and prevalent rheumatological diseases (e.g., rheumatoid arthritis, Sjögren's disease, and systemic lupus erythematosus).[11,12,13,14,15,16,17,18,19] Blockade of FcRn has the potential to reduce overall autoantibody levels while preserving immune function without causing broad immunosuppression. Blockade of IgG binding to FcRn in the placenta is also believed to prevent transplacental transfer of maternal alloantibodies to the fetus.[11,20]

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 both 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 January 1, 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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