Media contact:

Bridget Kimmel
Mobile: (215) 688-6033

Investor contact:

Raychel Kruper
Office: (732) 524-6164

Janssen Reports Positive Topline Phase 2 Results for Nipocalimab in Pregnant Individuals at High Risk for Severe Hemolytic Disease of the Fetus and Newborn (HDFN)

There are currently no approved therapeutics for the treatment of HDFN which, in severe cases, can cause life-threatening anemia in the fetus

SPRING HOUSE, PENNSYLVANIA, February 6, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced positive topline results from the proof-of-concept Phase 2 open-label UNITY clinical trial for the treatment of pregnant adults at high risk for severe hemolytic disease of the fetus and newborn (HDFN). HDFN is a serious and rare condition which can cause life-threatening anemia in the fetus. It occurs when the blood types of a pregnant individual and their fetus are incompatible.[1] The trial met the primary endpoint, with the majority of pregnant patients who received nipocalimab achieving a live birth at or after the gestational age (GA) of 32 weeks, without the need for an intrauterine transfusion (IUT) throughout their entire pregnancy. During the treatment period of approximately 20 weeks, nipocalimab demonstrated a safety profile that supports further development of the treatment in HDFN.

Nipocalimab was granted Fast Track designation in July 2019 and orphan drug

status in June 2020 by the U.S. Food and Drug Administration (FDA), and orphan medicinal product designation by the European Medicines Agency in October 2019 for HDFN.

"These early results represent an important step towards delivering a potential medication for expectant mothers at high risk of severe HDFN, and we are encouraged by what this treatment could mean for families affected by this potentially devastating disease. I would like to thank our patients and investigators for their participation and commitment in completing UNITY," said Katie Abouzahr, M.D., Vice President, Autoantibody Portfolio Development Leader, Janssen Research & Development, LLC. "We look forward to sharing the full Phase 2 results of the UNITY trial at an upcoming scientific medical meeting while we continue to plan for a pivotal Phase 3 trial."

About UNITY

UNITY is a global, multicenter, open-label, non-blinded Phase 2 clinical trial to evaluate the safety and efficacy of nipocalimab for the treatment of pregnant adults at high risk for severe HDFN.[2] In the trial, 14 participants received once weekly intravenous infusions. The primary endpoint was live birth at or after GA of 32 weeks, without a need for an intrauterine transfusion (IUT) throughout the entire pregnancy. Adverse events were monitored up to approximately 24 weeks post-delivery for parents and up to approximately 96 weeks post-birth for children.[2]

About HDFN

HDFN is a rare autoantibody-driven disease where antibodies produced in a pregnant person's immune system cross the placenta and attack fetal red blood cells — causing fetal hemolysis leading to anemia.[1] The severe form of HDFN, which is categorized as an ultra-rare disease, can lead to life-threatening anemia.[3] Today, there are no approved therapeutics for the treatment of HDFN, and pregnancies affected by severe HDFN may necessitate repeated IUTs. IUTs are invasive, technically complex surgical procedures performed by specialists that may be associated with an increased rate of fetal mortality and premature birth.[4] According

to the *American Journal of Obstetrics and Gynecology*, in the U.S., it is estimated that up to 80 out of every 100,000 pregnancies are affected by HDFN each year.[5]

About Nipocalimab

Nipocalimab is an investigational, high affinity, fully human, aglycosylated, effectorless, monoclonal antibody that is believed to selectively block the Fc receptor (FcRn) to reduce levels of circulating immunoglobulin G (IgG) antibodies, including autoantibodies and alloantibodies that underlie multiple conditions. Nipocalimab is being studied in all three segments of autoantibody-driven disease: maternal fetal diseases mediated by maternal autoantibodies – also known as 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 rheumatologic diseases (e.g., rheumatoid arthritis, Sjögren's syndrome, and systemic lupus erythematosus).[2,6-14] Blockade of FcRn by nipocalimab has the potential to reduce overall autoantibody levels while maintaining immune function. FcRn blockade is also believed to prevent placental transfer of maternal alloantibodies to the fetus.[2,15] Currently, nipocalimab is the only therapy in clinical development for the treatment of alloimmunized pregnant adults at risk of severe HDFN.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal.

Janssen Research & Development, LLC is a part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding nipocalimab product development. 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, any of the other Janssen Pharmaceutical Companies 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 2, 2022, 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 the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

# # #

References

1. Medline Plus. Hemolytic disease of the newborn. Available at: https://medlineplus.gov/ency/article/001298.htm. Accessed: January 18, 2023.
2. Clinicaltrials.gov. A Multicenter, Open-label Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Pharmacodynamics of M281 Administered to Pregnant Women at High Risk for Early Onset Severe Hemolytic Disease of the Fetus and Newborn (HDFN). Identifier: NCT03842189. Available at: https://clinicaltrials.gov/ct2/show/NCT03842189. Accessed: January 18, 2023.
3. Delaney M, Matthews DC. Hemolytic disease of the fetus and newborn: managing the mother, fetus, and newborn. *Hematology Am Soc Hematol Educ Program*. (2015) 2015(1):146-151. doi: https://doi.org/10.1182/asheducation-2015.1.146. Accessed: January 18, 2023.
4. de Winter DP, Kaminski A, Tjoa ML, et al. Hemolytic disease of the fetus and newborn: systematic literature review of the antenatal landscape. *BMC Pregnancy and Childbirth*. 2023;23(12). doi: https://doi.org/10.1186/s12884-022-05329-z. Accessed: January 18, 2023.
5. Ling L, Yu D, Gleeson CD, Moise K. Estimation of hemolytic disease of the newborn in the United States from 1996-2010 [SMFM Poster 968]. *Am J Obstet Gynecol*. 2021;224(Suppl2):S600-S601. doi: https://doi.org/10.1016/j.ajog.2020.12.993. Accessed: January 18, 2023.
6. ClinicalTrials.gov Identifier: NCT05265273. Available at: https://clinicaltrials.gov/ct2/show/NCT05265273. Accessed January 18, 2023.
7. ClinicalTrials.gov Identifier: NCT04951622. Available at: https://clinicaltrials.gov/ct2/show/NCT04951622. Accessed January 18, 2023.
8. ClinicalTrials.gov Identifier: NCT05327114. Available at: https://clinicaltrials.gov/ct2/show/NCT05327114. Accessed January 18, 2023.
9. ClinicalTrials.gov Identifier: NCT03842189. Available at: https://clinicaltrials.gov/ct2/show/NCT03842189. Accessed January 18, 2023.
10. ClinicalTrials.gov Identifier: NCT04119050. Available at: https://clinicaltrials.gov/ct2/show/NCT04119050. Accessed January 18, 2023.
11. ClinicalTrials.gov Identifier: NCT04968912. Available at: https://clinicaltrials.gov/ct2/show/NCT04968912. Accessed January 18, 2023.
12. ClinicalTrials.gov Identifier: NCT04882878. Available at: https://clinicaltrials.gov/ct2/show/NCT04882878. Accessed January 18, 2023.
13. ClinicalTrials.gov Identifier: NCT05379634. Available at: https://clinicaltrials.gov/ct2/show/NCT05379634. Accessed January 18, 2023.
14. ClinicalTrials.gov Identifier: NCT04991753. Available at: https://clinicaltrials.gov/ct2/show/NCT04991753. Accessed January 18, 2023.
15. Roy S, Nanovskaya T, Patrikeeva S, et al. M281, an anti-FcRn antibody, inhibits IgG transfer in a human ex vivo placental perfusion model. *Am J Obstet Gynecol*. 2019;220(5):498 e491-498 e499. Accessed: January 18, 2023.