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NEWS RELEASE

New nipocalimab data published in mAbs journal details differentiated molecular design, clinical profile and potential of nipocalimab to treat IgG-driven alloantibody and autoantibody diseases

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Published results reinforce the high-affinity binding and immunoselective properties of nipocalimab, which has been shown to reduce IgG levels by >75%, including autoantibodies, potentially without affecting other immune functions

SPRING HOUSE, Pa., Feb. 13, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced the publication of data detailing the differentiated molecular properties of nipocalimab, an investigational neonatal Fc receptor (FcRn) blocker, **in mAbs**.[a] This publication highlights the selective, targeted and high-affinity binding properties of nipocalimab which support its differentiated potential as a treatment option for immunoglobulin G (IgG)-driven alloantibody and autoantibody diseases.[1]

Nipocalimab is a fully human IgG-1 monoclonal antibody that binds to FcRn, resulting in the reduction of circulating IgG levels including pathogenic IgG autoantibodies.[1] The studies established that nipocalimab binds both specifically and with high, pH-independent affinity to FcRn.[1] These preclinical studies also established the relationship between FcRn binding and the inhibition of IgG recycling, revealing that nipocalimab achieves time and dose-dependent IgG reductions of greater than 75% without affecting IgG production and without detectable effects on other adaptive and innate immune functions.[1] The pH-independent nature of the binding, also noted in this publication, is one factor contributing to the ability to investigate nipocalimab in alloimmune diseases of pregnancy.[1] The mechanism of action of nipocalimab was assessed through in vitro and in vivo studies, and attributes noted in the publication are consistent with clinical Phase 1, 2 and 3 studies of nipocalimab.[1] The clinical

significance is not yet known.

"There is a critical need for additional approved, targeted and effective treatments with proven safety profiles to help alleviate the burden of severe IgG-driven autoantibody diseases, like generalized myasthenia gravis," said Pushpa Narayanaswami, M.D., FAAN, Vice Chair of Clinical Operations, Department of Neurology at the Beth Israel Deaconess Medical Center, Boston M.A. and Professor of Clinical Neurology at Harvard Medical School, and an author of the publication.[b] "I am excited to be a part of this important research, which underscores how the differentiated characteristics of nipocalimab may help to effectively address the underlying causes of these conditions."

Editor's notes:

a. mAbs is a multidisciplinary, peer-reviewed, open access journal dedicated to the art and science of antibody research and development.
b. Dr. Pushpa Narayanaswami has provided consulting, advisory and speaking services to Johnson & Johnson. She has not been paid for any media work.

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. 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.[2,3,4,5,6,7,8,9,10] Blockade of IgG binding to FcRn in the placenta is also believed to limit transplacental transfer of maternal alloantibodies to the fetus.[11,12]

The U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have granted several key designations to nipocalimab including:

- U.S. FDA Fast Track designation in hemolytic disease of the fetus and newborn (HDFN) and warm autoimmune hemolytic anemia (wAIHA) in July 2019, gMG in December 2021 and fetal neonatal alloimmune thrombocytopenia (FNAIT) in March 2024
- 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 Sjögren's disease in November 2024
- U.S. FDA granted Priority Review in gMG in Q4 2024

- EU EMA Orphan medicinal product designation for HDFN in October 2019

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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 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 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. 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.

REFERENCES

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