Momenta Pharmaceuticals Announces Fast Track Designation for M281 (nipocalimab) in Hemolytic Disease of the Fetus and Newborn (HDFN)

July 30, 2019

CAMBRIDGE, Mass., July 30, 2019 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq: MNTA), a biotechnology company focused on discovering and developing novel biologic therapeutics to treat rare immune-mediated diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for M281, Momenta's IgG1 monoclonal antibody targeting FcRn, in Hemolytic Disease of the Fetus and Newborn (HDFN). HDFN is a serious blood disorder in a fetus or newborn that occurs when red cell incompatibility exists between the blood types of a mother and baby.

Additionally, the United States Adopted Names Council (USAN), in consultation with the World Health Organization (WHO) International Nonproprietary Names Expert Committee, has adopted nipocalimab as the nonproprietary (generic) drug name for M281.

"Obtaining Fast Track designation highlights the critical need for non-invasive, safe and effective treatment options for women at risk of HDFN. In addition, there is a broad range of rare and severe allo and autoantibody disorders in maternal fetal medicine that could benefit from the activity of nipocalimab," said Craig Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "We are pleased to receive Fast Track designation for nipocalimab in this indication and look forward to continuing our interactions with the FDA as development progresses."

HDFN is caused by the transfer of alloantibodies from the mother's circulatory system to the fetus during pregnancy. This transfer enables maternal antibodies to attack the red blood cells of the fetus, resulting in significant morbidity and mortality. HDFN affects an estimated 4,000 to 8,000 pregnancies each year in the U.S. with limited options available for treatment. The current standard-of-care is intrauterine blood transfusions, which are invasive and may be associated with significant complications.

Nipocalimab (M281), an investigational product, is a fully human, anti-FcRn, aglycosylated IgG1 monoclonal antibody intended to reduce the risk and severity of fetal anemia and the resulting morbidities. Nipocalimab (M281) blocks FcRn-mediated IgG recycling, thereby reducing the pathogenic alloantibodies in maternal circulation and blocks placental transfer of maternal IgG, including pathogenic alloantibodies, to the fetus.

Nipocalimab (M281) is the focus of the Unity clinical trial in HDFN led by Kenneth Moise, MD, a maternal-fetal medicine specialist at The University of Texas Health Science Center at Houston (UTHealth). Moise is the principal investigator for the global study. He is also a professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences and Department of Pediatric Surgery with McGovern Medical School at UTHealth and co-director of The Fetal Center at Children's Memorial Hermann Hospital in collaboration with UT Physicians. McGovern Medical School at UTHealth is the first site in the U.S. to be open for enrollment in this global clinical trial. Additional clinical trial information can be found here.

About the FDA's Fast Track Program

The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs that treat serious conditions and fill unmet medical needs. A drug granted Fast Track Designation may be eligible for several benefits, including more frequent meetings and communications with the FDA and, if certain criteria are met, the potential for Accelerated Approval, Priority Review or Rolling Review of a Biologics License Application (BLA).

About Momenta

Momenta Pharmaceuticals is a biotechnology company with a validated innovative scientific platform focused on discovering and developing novel therapeutics to treat rare, immune-mediated diseases and advancing its late stage biosimilar portfolio. The company is headquartered in Cambridge, MA.

To receive additional information about Momenta, please visit the website at https://www.momentapharma.com/, which does not form a part of this press release.

Forward-Looking Statements

Statements in this press release regarding management's future expectations, beliefs, intentions, goals, strategies, plans or prospects, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to the timing of regulatory approval and launch of our product candidates; development timelines; the Company's ability to meet its development and strategic goals; market potential and revenue of our products and product candidates, design, timing and goals of clinical trials; the use, efficacy, safety, potency, tolerability, convenience and commercial potential of our product candidates. Forward-looking statements may be identified by words such as "believe," "continue," "plan to", "potential," "will," and other similar words or expressions, or the negative of these words or similar words or expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors, including those referred to under the section

"Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 filed with the Securities and Exchange Commission, as well as other documents that may be filed by the Company from time to time with the Securities and Exchange Commission. As a result of such risks, uncertainties and factors, the Company's actual results may differ materially from any future results, performance or achievements discussed in or implied by the forward-looking statements contained herein. The Company is providing the information in this press release as of this date and assumes no obligations to update the information included in this press release or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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