



Momenta Pharmaceuticals Announces Publication of New Data Supporting M281 as First Anti-FcRn Antibody to Inhibit Maternal-Fetal IgG Transfer in the Human Term Placenta

March 21, 2019

- Data supports M281's potential to prevent placental transfer of disease-inducing antibodies from mother to fetus in alloimmune and autoimmune diseases of the fetus and newborn
- Global multi-center Phase 2 study of M281 in hemolytic disease of the fetus and newborn (HDFN) now active following regulatory approvals

CAMBRIDGE, Mass., March 21, 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 new preclinical data for M281, its potentially best-in-class anti-FcRn antibody, was published in the **American Journal of Obstetrics & Gynecology**. The data show that M281 inhibits maternal to fetal IgG transfer in the human ex vivo term placental perfusion model, while showing minimal transfer itself to fetal circulation.

The published study entitled, "[M281, an anti-FcRn antibody, inhibits IgG transfer in a human ex vivo placental perfusion model](#)," was conducted in collaboration with the laboratory of Dr. Tatiana Nanovskaya at the University of Texas Medical Branch.

"This study in the gold standard model of the human term placenta showed that M281 has the potential to block the transfer of IgG from maternal to fetal circulation through late pregnancy. Prevention of maternal to fetal transfer of pathogenic antibodies through late pregnancy, the period with the highest placental IgG transfer, is a mechanism that may benefit alloimmune and autoimmune diseases of the fetus and newborn which can be potentially life threatening," said Santiago Arroyo, M.D., Ph.D., Senior Vice President of Development and Chief Medical Officer of Momenta Pharmaceuticals. "Additionally, M281 itself showed insignificant transfer to the fetal circulation, which could minimize exposure of the fetus to M281. With lowering of systemic IgG, as seen in our Phase 1 study, and the potential to block placental transfer of pathogenic antibodies, we believe M281 has broad potential to treat alloimmune and autoimmune diseases of pregnancy, as well as a number of autoimmune diseases.

"We are also pleased to announce that we obtained appropriate regulatory approvals in the U.S., Canada, and several EU countries, and that clinical sites are in the process of being activated globally for our multicenter clinical trial evaluating M281 in the prevention of early antenatal hemolytic disease of the fetus and newborn, a disease with high fetal mortality and infant morbidity," continued Dr. Arroyo.

About M281

M281 is a fully human anti-neonatal Fc receptor (FcRn), aglycosylated immunoglobulin G (IgG₁) monoclonal antibody, engineered to reduce circulating pathogenic IgG antibodies by blocking endogenous IgG recycling via FcRn. Momenta previously reported positive data showing safety, tolerability and proof of mechanism for M281 in a Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) study of normal human volunteers. Over the 98-day MAD study, M281 exhibited no serious adverse events, was well tolerated, and decreased circulating IgG levels up to 89% with a mean reduction of 84%.¹ M281 is currently being evaluated in Phase 2 studies in generalized myasthenia gravis² and in early onset antenatal HDFN³ with plans for an additional Phase 2 autoimmune study later this year.

About Hemolytic Disease of the Fetus and Newborn (HDFN)

Hemolytic disease of the fetus and newborn is a rare and potentially life-threatening condition that affects approximately 4,000-8,000 pregnancies each year in the U.S. alone. The disease is caused by antibodies from the mother which target proteins (also called antigens) on the fetal red blood cells (a process known as red cell alloimmunization). The most common antigen is RhD, although other antigens such as Rhc, RhE and Kell may also be involved in the process.

During pregnancy, antibodies can cross the placenta and bind to the antigens on the surface of the fetus' red blood cells, leading to fetal red blood cell destruction and anemia. Anemia causes less oxygen to be delivered to all the fetal tissues and can lead to organ damage and ultimately lead to fetal heart failure and even fetal death. In addition, severe HDFN can, in some cases, result in long-term neurodevelopmental delay including cerebral palsy and bilateral deafness. Intrauterine blood transfusions are the current standard of care, as there are no FDA-approved drugs to treat women at risk of HDFN.

About Momenta

Momenta is a biotechnology company with a validated innovative scientific platform focused on discovering and developing novel therapeutics to treat rare, immune-mediated diseases. Momenta's product candidate, M281, is a potentially best-in-class anti-FcRn antibody; M254, is a hyper-sialylated human immunoglobulin (hslgG) designed as a high potency alternative to intravenous immunoglobulin (IVIg); and M230 (CSL730), is a potential first-in-class novel recombinant Fc multimer being developed in collaboration with CSL. Momenta also has a focused pipeline of two biosimilar candidates: M923, Momenta's wholly-owned proposed biosimilar to HUMIRA[®], and M710, a proposed biosimilar to EYLEA[®] being developed in collaboration with Mylan. Momenta's two FDA-approved complex generic products, enoxaparin sodium injection and Glatopa[®] (glatiramer acetate injection), are marketed by its collaboration partner, Sandoz.

To learn more about Momenta, please visit www.momentapharma.com, which does not form a part of this press release.

Momenta's logo, trademarks, and service marks are the property of Momenta Pharmaceuticals, Inc. All other trade names, trademarks, or service marks are property of their respective owners.

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 statements about the design, timing and goals of clinical trials, including gold standard models, and the availability and timing of reporting results; the use efficacy, safety, tolerability, convenience and commercial potential of our product candidates, including their potential as best-in-class agents. 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 the risk of the unpredictable nature of early stage development efforts for our product candidates; safety, efficacy or tolerability problems with our product candidates; unexpected adverse clinical trial results; and those referred to under the section "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 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.

INVESTOR CONTACT:
Patty Eisenhour
Momenta Pharmaceuticals
1-617-395-5189
IR@momentapharma.com

MEDIA CONTACT:
Karen Sharma
MacDougall Biomedical Communications
1-781-235-3060
Momenta@macbiocom.com

¹ [Clinical Pharmacology & Therapeutics](#). November 2018

"[M281, an Anti-FcRn Antibody: Pharmacodynamics, Pharmacokinetics, and Safety Across the Full Range of IgG Reduction in a First-in-Human Study](#)". Ling LE, Hillson JL, Tiessen RG, Bosje T, van Iersel MP, Nix DJ, Markowitz L, Cilfone NA, Duffner J, Streisand JB, Manning AM, Arroyo S. Clin Pharmacol Ther. 2018 Nov 6. doi: 10.1002/cpt.1276. [Epub ahead of print].

² [Clinicaltrials.gov](#) identifier NCT03772587

³ [Clinicaltrials.gov](#) identifier NCT03842189



Source: Momenta Pharmaceuticals, Inc.