



Momenta Pharmaceuticals Announces Oral Presentation of New Data for M281 at the Society for Maternal-Fetal Medicine 2019 Annual Meeting

February 7, 2019

- Study highlights ability of M281 to inhibit transfer of immunoglobulin G from maternal to fetal circulation in *ex vivo* placental perfusion model
- M281 currently being evaluated in an international Phase 2 study in Hemolytic Disease of the Fetus and Newborn (HDFN)

CAMBRIDGE, Mass., Feb. 07, 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 the selection of new research for its product candidate, M281, for an oral presentation at the Society for Maternal-Fetal Medicine (SMFM)'s 39th Annual Pregnancy Meeting. These data demonstrate the ability of M281 to inhibit the transfer of immunoglobulin G from maternal to fetal circulation with minimal transfer of M281 itself in a human *ex vivo* placental transfer model.

"We believe M281 has the ability to be a first-in-class therapy for women carrying a fetus who are at high risk of suffering from early onset severe HDFN. These data highlight the potential that M281 is able to inhibit IgG transfer from mother to fetus across the human placenta. Placental blockade to prevent pathogenic antibody transfer is believed to be a key mechanism for preventing the exposure of the fetus to pathogenic maternal antibodies," said Santiago Arroyo, M.D., Ph.D., Senior Vice President of Development and Chief Medical Officer of Momenta Pharmaceuticals. "With an international Phase 2 study now underway, we look forward to opening sites and enrolling patients in what we believe will be an important study in this unmet patient population."

Presentation Details:

Title: M281, an Anti-FcRn Antibody, Inhibits IgG Transfer in a Human Ex Vivo Placental Perfusion Model (Basic Science I, Abstract 32)

Date: Thursday, February 14, 2019

Time: 1:30p.m. – 1:45p.m. PT

Location: Augustus Ballroom 5-6, Caesar's Palace, Las Vegas, Nevada

Presentation: Materials will be available for download after the formal presentation at: [Momenta Events and Presentations](#)

The study demonstrates the ability of M281 to inhibit transfer of immunoglobulin G from maternal to fetal circulation with minimal transfer of M281 itself in the human *ex vivo* placental transfer model. This study, together with the completed first-in-human and nonclinical reproductive toxicology studies, support the potential for M281 to prevent transfer of pathogenic maternal antibodies to the fetus.

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 is the standard of care today as there are currently no FDA-approved drugs to treat women at risk of HDFN.

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%.

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.

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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 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

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Source: Momenta Pharmaceuticals, Inc.