Momenta Pharmaceuticals Announces Publication of Phase 1 Study Data for Anti-FcRn Antibody, M281

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Full data shows safety, tolerability and proof-of-mechanism in healthy volunteers

CAMBRIDGE, Mass., Nov. 07, 2018 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq: MNTA) today announced the publication of results from its Phase 1 study of M281 in healthy volunteers in the online edition of the peer-reviewed journal Clinical Pharmacology & Therapeutics. The paper, containing the full data from the Phase 1 study, is entitled M281, an Anti-FcRn Antibody: Pharmacodynamics, Pharmacokinetics and Safety across the Full Range of IgG Reduction in a First-In-Human Study**.** The paper will also appear in an upcoming print edition of the journal. A link to the online article can be accessed here: Link

"We are encouraged by the rapid onset and duration of target receptor occupancy, maximal reduction of circulating IgGs, and dose-dependent effect observed in this study, which demonstrates that M281 safely functions as designed in healthy volunteers and validates its mechanism," said Santiago Arroyo, M.D., Ph.D., Senior Vice President of Development and Chief Medical Officer of Momenta Pharmaceuticals. "These results support M281's continued development as a potential best-in-class anti-FcRn treatment for patients with immune-mediated diseases. We look forward to advancing the program into two Phase 2 studies, one in myasthenia gravis and one in hemolytic disease of the fetus and newborn, in the fourth quarter of 2018."

The Phase 1 randomized, double-blind, placebo-controlled single and multiple ascending dose study evaluated the safety, tolerability, pharmacokinetics and pharmacodynamics of M281 in 50 healthy volunteers over a 98-day period. M281 exhibited rapid onset of target receptor occupancy, dose-dependent pharmacodynamics, a self-limited IgG decrease to a mean maximum percent reduction of approximately 84% of baseline, and loss of target occupancy and IgG recovery observed at consistent times after the last dose. Single doses up to 60 mg/kg or 15 or 30 mg/kg administered weekly for up to 4 weeks by intravenous infusion were well-tolerated with no serious adverse events, few moderate adverse events (AEs) and a low incidence of other AEs, similar to placebo treatment.

About M281, anti-FcRn antibody
M281 is a fully human anti-neonatal Fc receptor (FcRn), aglycosylated immunoglobulin G (IgG_1) monoclonal antibody, engineered to reduce circulating pathogenic IgG antibodies, by blocking endogenous IgG recycling via FcRn. Momenta 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%. Momenta plans to commence two Phase 2 proof of concept studies, one in myasthenia gravis (MG) and one in hemolytic disease of the fetus and newborn (HDFN), in the fourth quarter of 2018.

About Momenta Pharmaceuticals
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 lead product candidate, M281, is a potentially best-in-class anti-FcRn antibody; M254, is a hyper-sialylated human immunoglobulin (hsIgG) 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: M710, a proposed biosimilar to EYLEA® being developed in collaboration with Mylan, and M923, Momenta's wholly-owned proposed biosimilar to HUMIRA®. 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.

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 clinical development plans and timing for, market potential of, and safety and efficacy of M281. 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 that the costs of the restructuring actions will exceed the Company's current expectations; the risk that the Company will not achieve the anticipated cost savings from the restructuring actions; and those referred to under the section "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended June 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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