June 9, 2016

Momenta Pharmaceuticals Initiates Phase 1 Trial of M281, an Anti-FcRn Monoclonal Antibody

CAMBRIDGE, Mass., June 09, 2016 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (NASDAQ:MNTA), a biotechnology company specializing in the characterization and engineering of complex drugs, today announced the dosing of the first healthy volunteers in a Phase 1 randomized, double-blind, placebo-controlled, ascending-dose cohort study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of M281, an anti-FcRn monoclonal antibody, for the treatment of autoimmune diseases.

"The preclinical data we presented at ASH in December 2015 supported the evaluation of M281 as a strategy for the rapid and reversible suppression of pathogenic autoantibodies or alloantibodies in the setting of a variety of autoimmune diseases," said Jim Roach, M.D., Senior Vice President of Development and Chief Medical Officer of Momenta Pharmaceuticals. "The initiation of this trial advances our initiative to develop a best-in-class monoclonal antibody for the treatment of antibody-mediated diseases with high unmet medical needs. We anticipate presenting the data from this trial in the second half of 2017."

M281 is a fully human IgG1 monoclonal antibody that targets the IgG-binding site of FcRn. In preclinical models, M281 potently antagonizes FcRn binding of IgGs and rapidly diminishes circulating levels of IgG antibodies, the primary pathogenic agent in a number of autoimmune diseases.

This study will enroll up to approximately 72 healthy volunteers depending on the number of cohorts enrolled. Part 1 of the study will assess ascending doses of M281 administered as a single dose. Part 2 will assess ascending doses of M281 administered as repeated weekly or twice-weekly doses over 28 days.

About Momenta Pharmaceuticals

Momenta Pharmaceuticals is a biotechnology company specializing in the detailed structural analysis of complex drugs and is headquartered in Cambridge, MA. Momenta is applying its technology to the development of generic versions of complex drugs, biosimilar and potentially interchangeable biologics, and to the discovery and development of novel therapeutics for oncology and autoimmune indications.

To receive additional information about Momenta, please visit the website at www.momentapharma.com, which does not form a part of this press release. The company'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, including without limitation statements regarding future evaluation and development of M281, clinical trial design and the timing of availability and presentation of data from clinical trials, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by terminology such as "anticipate," "initiative," "potentially," "strategy," "target," "will" or similar terms, variations of such terms or the negative of those terms. Such forward-looking statements involve known and unknown risks, uncertainties and other factors referred to in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 filed with the Securities and Exchange Commission under the section "Risk Factors," as well as other documents that may be filed by Momenta 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. Momenta 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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