Momenta Pharmaceuticals Reports Positive Top-Line Phase 1 Data Showing Proof of Mechanism for M281, an Anti-FcRn Monoclonal Antibody, in Healthy Volunteers

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M281 data shows safety and tolerability with no serious adverse events

CAMBRIDGE, Mass., Jan. 05, 2018 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA), a biotechnology company specializing in the characterization and engineering of complex drugs, today reported positive top-line 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%.

M281 is a fully human anti-neonatal Fc receptor (FcRn) aglycosylated immunoglobulin G (IgG_1) monoclonal antibody, engineered to reduce circulating pathogenic IgG antibodies, in excess of that achieved by any current treatments, by completely blocking endogenous IgG recycling via FcRn.

“I could not be more pleased that M281’s ability to lower IgG to target levels with a favorable safety profile worked precisely as we had designed. These data support M281’s potential as a best-in-class anti-FcRn therapeutic for the high unmet medical needs in immune-mediated disorders,” said Craig Wheeler, President and CEO, Momenta Pharmaceuticals. “M281 has been engineered as an effectorless, high affinity, pH insensitive monoclonal antibody to provide benefits that impact patients’ lives. We plan to finalize our development strategy and initiate a proof of concept clinical trial in the second half of 2018, pending regulatory feedback.”

The Phase 1 randomized, double-blind, placebo-controlled study evaluated the safety, tolerability, pharmacokinetics and pharmacodynamics of M281.

SAD: The single ascending dose portion of the study enrolled five cohorts with a total of 34 healthy adult volunteers and showed that a single dose of M281 achieved up to an 80% reduction of circulating IgG antibodies.

MAD: The multiple ascending dose portion of the study assessed M281 in two cohorts, administered in four weekly doses to 16 healthy adult volunteers and showed predictable pharmacokinetics, and commensurate, controllable and reproducible reductions in circulating IgG. The data showed greater than 80% reduction in circulating IgG antibodies with a mean reduction of 84%.

M281 was well tolerated at all dose levels and no serious adverse events or unexpected safety findings were observed in either portion of the study.

Momenta plans to present the top line MAD results of the Phase 1 study at the 2018 J.P. Morgan Annual Healthcare Conference. Full data from the Phase 1 study will be presented at an upcoming Company presentation and future medical congresses.

About Momenta’s Novel Therapeutics Portfolio
Momenta’s novel therapeutics portfolio focuses on immune-mediated disorders with high unmet medical need and is developing three unique clinical phase assets (M281, M254, M230) purposefully designed to target the effects of pathogenic antibodies, whilst advancing discovery across rare immune-mediated disorders. M281 is a fully human anti-neonatal Fc receptor (FcRn) immunoglobulin G (IgG_1) monoclonal antibody, engineered to reduce circulating pathogenic IgG antibodies, in excess of that achieved by any current treatments, by completely blocking endogenous IgG recycling via FcRn. M254 is a hyper-sialylated immunoglobulin designed as a high potency alternative for intravenous immunoglobulin (IVIg) to remediate limitations of that therapeutic approach. Specifically, sialylation of the Fc region of IgG augments the anti-inflammatory attributes of IVIg. M230 (CSL730), being developed in collaboration with CSL, is a novel recombinant trivalent human IgG1 Fc multimer designed to block tissue damage mediated by immune complexes, through its enhanced avidity and affinity for Fc receptors.

About Momenta
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, biosimilars and potentially interchangeable biologics, and to the discovery and development of novel therapeutics for 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.

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 future development plans, proof of mechanism or proof of concept in future clinical trials or regulatory feedback related to 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 factors, including those referred to under the section "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, 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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