Momenta Pharmaceuticals Announces First Subject Dosed in Phase 1/2 Clinical Trial of M254, Hypersialylated Immunoglobulin G

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CAMBRIDGE, Mass., Jan. 29, 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 dosing of the first subject in the Phase 1/2 clinical trial of M254, hypersialylated Immunoglobulin G (hsIgG). The Phase 1/2 study will enroll normal healthy volunteers and patients with Immune Thrombocytopenic Purpura (ITP). The multi-part study includes single and multiple dose parts, and a placebo-controlled, randomized double-blinded cross-over study comparing M254 to IVIg.

“We believe M254 has the potential to be a significantly better option for patients than conventional IVIg. Our aim for this study is to show clinically what we have observed in extensive preclinical models, which is that hypersialylated IgG is substantially more potent than intravenous immunoglobulin G (IVIg) in ITP and other inflammatory disorders,” said Santiago Arroyo, M.D., Ph.D., Senior Vice President of Development and Chief Medical Officer of Momenta Pharmaceuticals. “We look forward to obtaining initial clinical data in the first half of 2020.”

The four part study will evaluate the safety, efficacy, pharmacokinetics, and pharmacodynamics of intravenous (IV) M254 in approximately 65 subjects, including healthy volunteers and patients with ITP. Parts A and B are double-blind, placebo-controlled, single ascending dose cohort studies in healthy volunteers and ITP patients, respectively. In Part C, ITP patients will receive M254 or IVIg in a cross-over dosing design, while in Part D, ITP patients will receive multiple doses of M254. The primary efficacy endpoint is an assessment of platelet response.

About Immune Thrombocytopenic Purpura (ITP)
ITP is a rare autoimmune disease that leads to excessive bruising and bleeding, which can affect children and adults, and can be acute or chronic. Abnormal autoantibodies bind to circulating platelet membranes leading to platelet destruction and subsequent reduction in the number of circulating platelets (thrombocytopenia). It is estimated that chronic ITP affects 30,000 – 60,000 patients in the U.S. Current therapies for ITP include IVIg, steroids, platelet production boosters (TPO receptor agonists) and splenectomy. Not all patients, however, have an adequate treatment response with existing therapies. As a result, there remains a significant unmet medical need for additional treatment options for patients with ITP.

About M254, Hypersialylated Immunoglobulin G
M254 is a hypersialylated human immunoglobulin G, engineered with significantly enhanced tetra-sialylation. In preclinical studies of ITP and other inflammatory diseases, M254 has shown an increase in potency of up to ten times that of conventional IVIg.

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 lead product candidate, M281, is a potentially best-in-class anti-FcRn antibody; M254, is a hypersialylated 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 its partner, 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.

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, enrollment and timing of clinical trials and the availability and timing of reporting results; the use, efficacy, safety, tolerability, convenience and commercial potential of our products and product candidates and 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 our early stage development efforts for our novel drug candidates; safety, efficacy or tolerability problems with our product candidates; unexpected 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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