Momenta Pharmaceuticals Launches Phase 2/3 Trial of M281 for the Treatment of Warm Autoimmune Hemolytic Anemia and is Granted FDA Fast Track Designation

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CAMBRIDGE, Mass., Aug. 01, 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, announced the launch of an adaptive Phase 2/3 clinical study for its FcRn inhibitor nipocalimab (M281) in warm Autoimmune Hemolytic Anemia (wAIHA). This follows the acceptance of its Investigational New Drug (IND) application by the U.S. Food and Drug Administration. The FDA has also granted Fast Track Designation for nipocalimab in wAIHA.

“wAIHA is a rare autoimmune disease with high unmet medical need and no labelled treatments. By targeting FcRn as a mechanism to reduce circulating levels of pathogenic IgG antibodies, nipocalimab could offer significant potential benefit for patients with this devastating severe immune mediated disease,” said Craig Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. “This study initiation is an important milestone for Momenta, marking the start of our third clinical study of nipocalimab in auto and alloimmune diseases. To date, nipocalimab has exhibited a best-in-class profile and we continue to believe in its broad market potential across a range of immune-mediated diseases. Moreover, if successful, this adaptive Phase 2/3 study could serve as a pivotal study which could enable nipocalimab to be the first treatment option for wAIHA patients.”

“There are no approved treatments for warm autoimmune hemolytic anemia and the current treatment options are associated with significant side effects,” said Howard A. Liebman, MD, MA, USC Norris Comprehensive Cancer Hospital. “Patients and families are seeking out new treatments without potential serious complicating factors.”

This randomized, double blind, placebo-controlled, multi-center, adaptive Phase 2/3 clinical trial will investigate the efficacy, safety and tolerability of nipocalimab (M281) in patients with wAIHA. Often used in rare diseases, adaptive study designs allow for modification of the study design and hypotheses based on interim analyses of the data. This strategy allows for greater flexibility and efficiencies in study design, which can benefit both sponsors and patients in diseases with large unmet need, as the amount of useful data collected is maximized.

About Warm Autoimmune Hemolytic Anemia

wAIHA is a rare autoimmune hemolytic anemia characterized by the destruction of red blood cells due to the presence of pathogenic IgG autoantibodies. Destruction of red blood cells results in severe anemia, leading to weakness and fatigue. As the disease progresses, and without safe and effective treatment, serious complications can develop. Up to 8% of wAIHA patients may die prematurely, with those experiencing active and uncontrolled hemolysis most at risk. Rates as high as 30% have been observed for wAIHA patients with severe disease admitted to an ICU. All suffer from serious complications from the disease and its associated treatments.

Nipocalimab (M281) Overview

Using proprietary antibody engineering technology, Momenta has developed nipocalimab (M281), a fully human, anti-FcRn, aglycosylated IgG1 monoclonal antibody.

In patients with wAIHA, nipocalimab is expected to rapidly ameliorate the physical and laboratory manifestations of the disease by blocking FcRn-mediated recycling of IgG and reducing circulating levels of antibodies, including the pathogenic autoantibodies that cause wAIHA.

Momenta previously reported positive data showing safety, tolerability and proof of mechanism for nipocalimab in a Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) study of normal human volunteers. Over the 98-day MAD study, nipocalimab exhibited no serious adverse events, was well tolerated, and decreased circulating IgG levels up to 89% with a mean reduction of 84%.

Nipocalimab is also being evaluated in two ongoing Phase 2 trials: the Vivacity-MG clinical trial, a randomized, double-blinded, placebo-controlled multi-dose trial in 60 generalized myasthenia gravis patients where top line data is anticipated in the second or third quarter of 2020; and the Unity trial, an open label Phase 2 clinical trial of nipocalimab in 15 pregnant women at high risk for early onset severe hemolytic disease of the fetus and newborn (HDFN), with top line data anticipated in 2021. Additional clinical trial information can be found here and patients and families can find more information at www.momentapharma.com.

About the FDA’s Fast Track Program

The FDA’s Fast Track program is designed to facilitate the development and expedite the review of drugs that treat serious conditions and fill unmet medical needs. A drug granted Fast Track Designation may be eligible for several benefits, including more frequent meetings and communications with the FDA and, if certain criteria are met, the potential for Accelerated Approval, Priority Review or Rolling Review of a Biologics License Application (BLA).

About Momenta

Momenta Pharmaceuticals is a biotechnology company with a validated innovative scientific platform focused on discovering and developing novel therapeutics to treat rare, immune-mediated diseases and advancing its late stage biosimilar portfolio. The company is headquartered in Cambridge, MA.

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 the timing of our regulatory filings for clinical development and marketing approval; the timing of regulatory approval and launch of our product candidates; development timelines; the Company’s ability to meet its development and strategic goals; market potential and revenue of our products and product candidates, design, timing and goals of clinical trials and the availability, timing and announcement of data and results; the use, efficacy, safety, potency, 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 those referred to under the section "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 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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