Momenta Pharmaceuticals Provides Update on US Regulatory Strategy for M923, Proposed Biosimilar to HUMIRA®

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CAMBRIDGE, Mass., Dec. 03, 2018 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq: MNTA), a biotechnology company with a validated scientific platform focused on discovering and developing novel therapeutics to treat rare, immune-mediated diseases, today announced a revised regulatory strategy in the United States for M923, Momenta's proposed biosimilar to HUMIRA. Momenta had previously guided that it planned to file a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in the fourth quarter of this year.

With the recent Abbvie agreement, Momenta will be able to commercialize M923 in the United States, pending regulatory approval, as early as November 20, 2023. Momenta has decided to delay the filing of the BLA, which may reduce program costs in 2019 without delaying potential US market entry for M923.

"The clarity on the US entry date provided by our settlement with Abbvie allows us to better align our regulatory and manufacturing strategies and enables us to defer expenses without impact to our launch timing," said Craig Wheeler, President and Chief Executive Officer of Momenta.

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 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: 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 timing of regulatory filings, the development and commercialization plans, including target launch dates, program costs for, and the potential of, M923. 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 program costs savings will not be achieved, that the marketing approval process is expensive, time-consuming and uncertain and may prevent the Company from obtaining approvals for the commercialization of M923; 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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