



Momenta Pharmaceuticals Announces Global Settlement with AbbVie to Enable Commercialization of M923, a Proposed Biosimilar to HUMIRA® (adalimumab)

November 6, 2018

CAMBRIDGE, Mass., Nov. 06, 2018 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq: MNTA) today announced that it has executed agreements with AbbVie Inc., providing license rights for the global launch of M923, Momenta's proposed biosimilar to HUMIRA. Under the terms of the agreements and subject to approval by health regulatory authorities, Momenta may launch M923 in the United States (US) on November 20, 2023 and in Europe upon approval by the European Medicines Agency. Momenta plans to submit a biologics license application for M923 to the US Food and Drug Administration in the fourth quarter of 2018 and a marketing authorization application in the European Union in the first half of 2019.

"We are pleased to have been able to work with AbbVie on these agreements as they provide clarity as to when we will have the opportunity to expand treatment access and provide an additional high-quality option for patients who suffer from chronic inflammatory diseases," said Craig Wheeler, President and Chief Executive Officer of Momenta.

Financial terms of this settlement are confidential.

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: M710, a proposed biosimilar to EYLEA® being developed in collaboration with Mylan, and M923, Momenta's wholly-owned proposed biosimilar to HUMIRA®. 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.

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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 for, development and commercialization plans for, including launch dates, 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 costs of the restructuring actions will exceed the Company's current expectations; the risk that the Company will not achieve the anticipated cost savings from the restructuring actions; and those referred to under the section "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended June 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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