Momenta Pharmaceuticals Announces Positive Outcome for Contracted Glatopa® (glatiramer acetate injection) Fill/Finish Manufacturer

January 30, 2018

-- McPherson, Kansas facility compliance status amended to Voluntary Action Indicated (VAI)--
-- VAI status provides the potential for the near-term FDA approval of Sandoz's Glatopa 40 mg ANDA--

CAMBRIDGE, Mass., Jan. 30, 2018 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA), a biotechnology company specializing in the characterization and engineering of complex drugs, today announced that the FDA has classified the outcome of its fourth quarter 2017 reinspection of Pfizer's McPherson facility as Voluntary Action Indicated (VAI). The Glatopa 40 mg ANDA remains under regulatory review, however, the Company believes the application review could be completed at any time in connection with the change to VAI status.

"We are extremely pleased with this outcome. This past year of uncertainty regarding the resolution of the McPherson facility warning letter has been difficult for Momenta and its shareholders, but with this announced change in status we believe we are well-positioned to gain marketing approval and launch our Glatopa 40 mg in the first half of 2018," stated Craig Wheeler, Momenta CEO. "We remain committed to our goal of providing patients with relapsing forms of multiple sclerosis a more affordable, high-quality treatment option."

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, biosimilar 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, including, without limitation, the timing of the completion of regulatory review and approval and launch of Glatopa 40 mg are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by terminology such as "believe," "expect," "plan," "unlikely," or similar terms, variations of such terms or the negative of those terms. Such forward-looking statements involve known and unknown risks, uncertainties and other factors referred to in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 filed with the Securities and Exchange Commission under the section "Risk Factors," as well as other documents that may be filed by Momenta 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. Momenta 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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