August 28, 2014

Momenta Pharmaceuticals Announces Abbreviated New Drug Application for Three-Times-a-Week Generic Copaxone Accepted for Review by FDA

CAMBRIDGE, Mass., Aug. 28, 2014 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals (Nasdaq:MNTA) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Abbreviated New Drug Application (ANDA) for a three-times-a-week generic COPAXONE® (glatiramer acetate injection, 40 mg/mL), submitted by Sandoz Inc., Momenta's development and commercialization partner for this product candidate.

Based on publicly-available information, Momenta believes that, should the ANDA be approved, it would be eligible for 180-day first-to-file exclusivity under Hatch-Waxman. The product could be on the market as early as the first quarter of 2017, assuming the Paragraph IV challenge is successful and adheres to customary Hatch-Waxman litigation timelines. Since the 40 mg/mL formulation contains the same drug substance as the 20 mg/mL ANDA currently under review by the FDA, Momenta anticipates the FDA review process can be completed within the same time frame.

"We are pleased to announce the acceptance of the ANDA for our three-times-a-week generic Copaxone for review by the FDA," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "This formulation will allow for a more affordable, three-times-a-week dosing regimen for patients with relapsing-forms of multiple sclerosis."

About Relapsing-Remitting Multiple Sclerosis (RRMS)

Multiple sclerosis is a devastating chronic disease of the central nervous system characterized by inflammation and neurodegeneration. RRMS, defined by inflammatory attacks on the protective coating of neurons (myelin) and characterized by intermittent bouts of symptoms, is the most common disease course at the time of diagnosis. Copaxone is among the leading products marketed for treatment of RRMS. It works by stopping the body from damaging its own nerve cells (myelin). In North America, Copaxone is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva.

About Momenta

Momenta Pharmaceuticals is a biotechnology company specializing in the detailed structural analysis of complex mixture 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 products.

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 statements relating to its beliefs and intentions related to litigation with Teva, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include but are not limited to our expectations regarding regulatory review, timing, and ANDA approval, Hatch-Waxman litigation and first-to-file exclusivity. Forward-looking statements can be identified by terminology such as "anticipate," "believe," "could," "could increase the likelihood," "hope," "target," "project," "goals," "potential," "predict," "might," "estimate," "expect," "intend," "is planned," "may," "should," "will," "will enable," "would be expected," "look forward," "may provide," "would" 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 June 30, 2014 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.

Copaxone® is a registered trademark of Teva Pharmaceuticals

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