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Momenta Pharmaceuticals Announces Supreme Court Decision to Remand Generic Copaxone(R) Case Back to CAFC

Supreme Court Decides to Change the Standard of Appellate Review for Claim Interpretation in Patent Law Cases

CAMBRIDGE, Mass., Jan. 21, 2015 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today announced that the United States Supreme Court has vacated the 2013 decision of the Court of Appeals for the Federal Circuit ("CAFC") which found several of the Copaxone (20 mg injection) patents, including the one patent expiring September 1, 2015, invalid for being indefinite. The Supreme Court has overturned the long standing practice whereby the CAFC reviewed a District Court's claim interpretation "de novo," without deference to the District Court's claim interpretation, and ruled that the CAFC must instead give deference to the district court's findings of fact on issues of claim interpretation. The Supreme Court did not rule on the validity or invalidity of the patents per se, but has sent the case back to the CAFC to be reheard under the new deference standard.

"We continue to believe that the patents should be held invalid under the Supreme Court's new standard for claim construction and we plan to aggressively pursue our case on remand," said Craig Wheeler, President and Chief Executive Officer of Momenta. "We expect that the CAFC could rehear the case and issue a new decision within a year. We remain optimistic that the ANDA for M356, our generic Copaxone, could be approved by the FDA in the near term, providing patients with a more affordable generic alternative for the treatment of multiple sclerosis."

The case involved patents asserted by Teva against Momenta for patent infringement associated with the submission of an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA) for generic Copaxone by Momenta's commercial partner for the product, Sandoz Inc. The case is Teva Pharmaceuticals v. Sandoz and Momenta and Mylan et al., case numbers 2012-1567, -1568, -1569, -1570. The asserted patents included eight listed in the FDA Orange Book and one non-Orange Book patent.

About M356, a generic version of Copaxone (glatiramer acetate injection)
M356 (glatiramer acetate injection) is a generic version of Copaxone, a synthetic polypeptide medicine, developed in collaboration with Sandoz and currently under review by FDA. Copaxone is prescribed for patients with relapsing-remitting multiple sclerosis, a chronic disease of the central nervous system characterized by inflammation and neurodegeneration. Copaxone is one of the leading products marketed for treating multiple sclerosis.

About Momenta
Momenta Pharmaceuticals is a biotechnology company specializing in the detailed structural and functional 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 oncology and 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. The company's logo, trademarks, and service marks are the property of Momenta Pharmaceuticals, Inc. All other trade names, trademarks, or service marks are property of their respective owners.

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 the outcome of litigation with Teva Pharmaceuticals and our ability to achieve approval of our generic Copaxone (M536) product, 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 "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 September 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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