



July 26, 2013

## **Momenta Pharmaceuticals Announces Potential for 2014 Market Entry of Generic Copaxone (R)**

### **Federal Circuit Invalidates 2015 Copaxone Patent**

CAMBRIDGE, Mass., July 26, 2013 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today announced that the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") invalidated several Copaxone patents asserted against the company by Teva Pharmaceuticals, including the only asserted patent to expire in September 2015. Today's decision narrows a 2012 decision by the District Court for the Southern District of New York (the "District Court") and potentially clears the way for market entry of generic Copaxone as early as May 2014, the expiration date of the remaining asserted patents, pending U.S. Food and Drug approval (FDA).

"We are extremely pleased with today's ruling," said Craig Wheeler, President and Chief Executive Officer of Momenta. "Given the decision, we and Sandoz will continue to work with FDA to advance review of the ANDA for generic Copaxone in order for this product to be approved and available to patients as soon as possible."

The case involved nine patents asserted by Teva for patent infringement associated with submission of an Abbreviated New Drug Application (ANDA) to FDA for generic Copaxone. The asserted patents included seven FDA Orange Book patents and one non-Orange Book patent expiring in May 2014 and one non-Orange Book patent expiring in September 2015. The case is *Teva Pharmaceuticals v. Sandoz and Momenta and Mylan et al.*, case numbers 2012-1567, -1568, -1569, -1570.

In 2012, the District Court found all nine patents valid and infringed and issued injunctions enjoining FDA from approving any ANDA for generic Copaxone until May 2014, and enjoining parties in the case from making, using, offering for sale, or selling generic Copaxone until September 2015. Today's decision means that the injunctions will be modified to reflect the Federal Circuit's decision, potentially permitting generic Copaxone to be available to patients when remaining asserted patents covering Copaxone expire in 2014.

The ANDA for generic Copaxone is under FDA review and continues to advance. Momenta and Sandoz remain confident that the ANDA will be approved under the 505(j) pathway as an interchangeable generic Copaxone.

### **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 the Orange Book**

The "Orange Book" is officially recognized as the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations.

### **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, biosimilars and potentially interchangeable biologics, and to the discovery and development of novel medicines.

To receive additional information about Momenta, please visit the website at [www.momentapharma.com](http://www.momentapharma.com), which does not form a part of this press release.

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## Special Note Regarding 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 generic Copaxone (M356) 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 March 31, 2013 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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