Momenta Pharmaceuticals Receives Regulatory Guidance On M-Enoxaparin ANDA

Company Expects to Submit Amendment to ANDA in Third Quarter, 2008

CAMBRIDGE, Mass., Apr 29, 2008 (PrimeNewswire via COMTEX News Network) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA), a biotechnology company specializing in the characterization and engineering of complex drugs, today announced that the Food and Drug Administration (FDA) has provided guidance regarding the Abbreviated New Drug Application (ANDA) for M-Enoxaparin. Momenta is developing M-Enoxaparin, a technology-enabled generic version of Lovenox (r), in collaboration with Sandoz, the generics division of Novartis AG.

Earlier this year, Momenta and Sandoz submitted a proposal to FDA for addressing the potential immunogenicity of M-Enoxaparin, in response to FDA's letter of November, 2007. On April 28, 2008, FDA responded to the proposal and provided additional guidance which indicated their general concurrence with the Company's approach and proposal. FDA also requested additional data from in vitro and in vivo animal tests, the testing of additional samples for tests previously proposed, and additional information regarding certain of the methods proposed. The agency has not requested human clinical trials at this time.

"We are pleased that the FDA has clarified our path forward for M-Enoxaparin by providing written direction regarding their expectations for our application," commented Craig A. Wheeler, Chief Executive Officer of Momenta. "We are still evaluating the FDA's guidance, but, based on our preliminary assessment, we hope to submit the amendment containing the requested additional data in the third quarter."

About Momenta

Momenta Pharmaceuticals is a biotechnology company specializing in the detailed structural analysis of complex mixture drugs. Momenta is applying its technology to the development of generic versions of complex drug products, as well as to the discovery and development of novel drugs. Momenta was founded in 2001 based on technology initially developed at Massachusetts Institute of Technology and is headquartered in Cambridge, MA.

Forward Looking Statements

Statements in this announcement regarding management's future expectations, beliefs, intentions, goals, strategies, plans or prospects, including statements relating to the FDA's assessment of the ANDA for M-Enoxaparin or the timing of submission of the amendment to the M-Enoxaparin ANDA, may constitute 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 Annual Report on Form 10-K for the year ended December 31, 2007 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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