December 1, 2014

Momenta Pharmaceuticals' Necuparanib Receives Fast Track Designation From the FDA for the Treatment of Patients With Metastatic Pancreatic Cancer

CAMBRIDGE, Mass., Dec. 1, 2014 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA), a biotechnology company specializing in the characterization and engineering of complex drugs, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the investigation of necuparanib, the Company's novel oncology drug candidate, as a first-line treatment in combination with Abraxane® and gemcitabine in patients with metastatic pancreatic cancer. Momenta recently announced the successful completion of Part A of the Phase 1/2 study and has initiated the Part B (Phase 2 proof-of-concept) study.

The FDA's Fast Track Drug Development Program is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. This designation allows for companies to interact with the FDA review team frequently to discuss issues such as study design, extent of safety data required to support approval, the structure and content of an NDA, and other critical issues. In addition, such a product could be eligible for accelerated approval and/or priority review if supported by clinical data at the time of BLA, NDA, or efficacy supplement submission. If the FDA determines, after preliminary evaluation of clinical data submitted by a sponsor, that a Fast Track product may be effective, the Agency may also consider reviewing portions of a marketing application before the sponsor submits the complete application.

"Receipt of Fast Track designation from the FDA further supports our belief in the potential of necuparanib to enhance overall survival rates in patients with metastatic pancreatic cancer, a disease for which there are very limited treatment options," said Jim Roach, MD, Chief Medical Officer of Momenta Pharmaceuticals. "We look forward to taking full advantage of the opportunities that Fast Track designation allows in order to maximize the possibility of an accelerated path to approval."

In October 2014, Momenta completed the Part A dose escalation component of the Phase 1/2 clinical trial evaluating necuparanib in combination with Abraxane and gemcitabine in patients with advanced metastatic pancreatic cancer, and reported positive top-line data. Part B of the Phase 1/2 trial, currently underway, is a randomized, controlled, proof-of-concept study to evaluate the antitumor activity of necuparanib in combination with Abraxane plus gemcitabine, versus Abraxane plus gemcitabine alone. Momenta expects data from Part B to be available in the first half of 2017.

About Necuparanib
Necuparanib (formerly M402) is a novel oncology drug candidate engineered to have a broad range of effects on tumor cells. The use of heparins to treat venous thrombosis in cancer patients has generated numerous reports of antitumor activity; however, the dose of these products has been limited by their anticoagulant activity. Leveraging its experience in deciphering the structure-function relationships of complex therapeutics, Momenta engineered necuparanib from unfractionated heparin to have significantly reduced anticoagulant activity while preserving relevant antitumor properties associated with heparins, such that higher doses could be administered to possibly further potentiate these antitumor effects. In June 2014, necuparanib received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of pancreatic cancer.

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, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to statements about the Company's future development of necuparanib, the expected availability of clinical trial data in the Phase 1/2 study, the eligibility of necuparanib for priority review or accelerated approval, and its potential to treat unmet medical needs in cancer. 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.

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