June 5, 2014

# Momenta Pharmaceuticals Receives Orphan Drug Designation for Necuparanib (Formerly M402) in Pancreatic Cancer

CAMBRIDGE, Mass., June 5, 2014 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) today announced that its novel oncology candidate, necuparanib (formerly M402), has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of pancreatic cancer.

"We are pleased to receive Orphan Drug Designation for necuparanib, which highlights the great need for new medications for patients suffering from pancreatic cancer," said Jim Roach MD, Chief Medical Officer of Momenta Pharmaceuticals. "We are encouraged by the progress of the program to date, and in the next several months, we anticipate completing Part A of our ongoing Phase 1/2 study of necuparanib in combination with Abraxane® and gemcitabine. We look forward to sharing the results from Part A and advancing the product into the Phase 2 part of the study in the second half of 2014."

The FDA's Orphan Drug Designation program provides orphan status to drugs and biologics intended to treat, diagnose or prevent rare diseases/disorders, defined as affecting fewer than 200,000 people in the U.S. This designation provides certain incentives, including federal grants, tax credits, waiver of PDUFA filing fees and a seven-year marketing exclusivity period against competition once the product is approved.

**About Necuparanib**

The United States Adopted Names (USAN) Council has recently adopted "necuparanib" as the unique non-proprietary name for M402. Necuparanib, a heparan sulfate mimetic, 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. Necuparanib, which is derived from unfractionated heparin, has been engineered to have significantly reduced anticoagulant activity while preserving the relevant antitumor properties of heparin. In the next several months, Momenta expects to complete the Part A dose escalation component of the Phase 1/2 trial evaluating necuparanib in combination with Abraxane® (nab-paclitaxel) and gemcitabine in patients with advanced metastatic pancreatic cancer, and to report clinical data from Part A in the second half of 2014. The company plans to initiate Part B of the study by the end of 2014. Part B will be 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.

**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, the Company's revenue, expenses, including the results and timing for necuparanib clinical trial results, 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 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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Source: Momenta Pharmaceuticals