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Momenta Resumes Patient Enrollment in the Necuparanib (MOM-M402-103) Phase 2 Study

CAMBRIDGE, Mass., Dec. 21, 2015 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (NASDAQ:MNTA) today announced that it has resumed patient enrollment in its ongoing Phase 2 portion of the trial "A Phase I/II, Two-Part, Multicenter Study to Evaluate the Safety and Efficacy of M402 in Combination with nab-Paclitaxel and Gemcitabine in Patients with Metastatic Pancreatic Cancer." Study enrollment was paused last month following Momenta's acceptance of recommendations from its Data Safety Monitoring Board (DSMB) to develop guidelines for diagnosing and managing thrombocytopenia, based on a limited number of specific toxicities observed in the study.

"We are pleased that following their review of the protocol amendment, the DSMB is supportive of resuming patient enrollment in our necuparanib study," said Jim Roach, M.D., Senior Vice President of Development and Chief Medical Officer of Momenta Pharmaceuticals. "Given the projected timelines to obtain Institutional Review Board approval of the protocol amendment across study sites, we now anticipate that the top-line data should be available in the second half of 2017."

About Necuparanib

Necuparanib (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. A Phase 2 randomized, double-blind, controlled study to evaluate the antitumor activity of necuparanib in combination with nab-paclitaxel (Abraxane[®]) plus gemcitabine, versus nab-paclitaxel plus gemcitabine alone in pancreatic cancer is currently underway. Necuparanib has received Orphan Drug and Fast Track designations 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 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.

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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 conduct of its necuparanib study; the timing of regulatory submissions and enrollment following the current enrollment pause; the availability and announcement of clinical data; and the review of the necuparanib study plans by the U.S. Food and Drug Administration. Forward-looking statements may be identified by words such as "anticipate," "believe," "continue," "could," "hope," "target," "project," "goal," "objective," "guidance," "plan," "potential," "predict," "might," "estimate," "expect," "intend," "may," "seek," "should," "will," "would," "look forward" and other similar words or expressions, or the negative of these words or similar words or expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, including those referred to under the section "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed with the Securities and Exchange Commission, as well as other documents that may be filed by the Company 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. The Company 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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