



November 13, 2015

## **Momenta Announces Temporary Pause of Patient Enrollment in the Necuparanib (MOM-M402-103) Phase 2 Study**

CAMBRIDGE, Mass., Nov. 13, 2015 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (NASDAQ:MNTA) today announced that it has put a temporary hold on 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," pending the institution of a protocol amendment following receipt of recommendations from its independent Data Safety Monitoring Board (DSMB).

The DSMB met to discuss a limited number of specific toxicities, including thrombocytopenia, risk of bleeding, and thromboembolic events. After thorough review, the DSMB found no safety signals to suggest the need to unblind results, close the study, or discontinue dosing in patients already enrolled in the trial. The DSMB did recommend that the company amend its protocol to standardize the approach to diagnosing and managing thrombocytopenia and consider holding new patient accrual until the amendment is instituted. The DSMB also noted that the causes of thrombocytopenia and subsequent bleeding in these patients can be multifactorial. The Company is assessing whether its protocol amendment and enrollment pause will delay release of top-line data beyond the first half of 2017.

"We support the DSMB's recommendations regarding the most appropriate path forward for the Phase 2 portion of the trial. As always, patient safety is our primary concern, and we will work diligently to institute their recommendations and resume enrollment in this study," stated Jim Roach, M.D., Senior Vice President of Development and Chief Medical Officer of Momenta Pharmaceuticals.

### **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<sup>®</sup>) 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](http://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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