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Momenta Pharmaceuticals Announces Top-Line Part A Results From Phase 1/2 Trial of Necuparanib in Patients With Pancreatic Cancer

Novel Oncology Candidate Necuparanib Well Tolerated in Part A; Dose Selected for Part B Proof-of-Concept Trial and Trial Initiation Underway

CAMBRIDGE, Mass., Oct. 9, 2014 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA), a biotechnology company specializing in the characterization and engineering of complex drugs, announced top-line results from the dose-escalation component (Part A) of the Phase 1/2 trial evaluating necuparanib in combination with Abraxane® (ABX; *nab*-paclitaxel) and gemcitabine (GEM) in patients with advanced metastatic pancreatic cancer (ClinicalTrials.gov Identifier NCT01621243). A dose was established to take forward into Part B (Phase 2) of the trial, which is a randomized, controlled, proof-of-concept study to evaluate the antitumor activity of necuparanib in combination with ABX and GEM, compared with ABX and GEM alone.

Part A is a Phase 1 study of escalating daily necuparanib doses in combination with 125 mg/m^2 ABX and 1000 mg/m^2 GEM (Days 1, 8, and 15 of each 28-day cycle) in patients with metastatic pancreatic cancer. The necuparanib starting dose was 0.5 mg/kg, which was increased via a modified 3+3 design until a maximum tolerated dose was determined. ABX was added to the treatment regimen starting with Cohort 3 following release of the Phase 3 ABX + GEM data last year. Thirty-seven patients (12 patients in the first two cohorts and 25 patients in the five subsequent cohorts) received necuparanib as of data cutoff and were included in the analyses. Top-line results included:

- The most common (≥30% of patients) AEs included anemia, fatigue, nausea, diarrhea, and vomiting - comparable to what has been observed for ABX and GEM alone.
- Twelve patients were treated with the combination regimen of necuparanib, ABX, and GEM and have completed the first 28-day cycle as of data cutoff. All 12 of these patients also had at least one follow up CT scan and were considered evaluable for radiographic response. Seven (58%) achieved a RECIST partial response (PR) and an additional 4 (33%) achieved stable disease (SD). Disease Control (the # of patients with Complete Response + PR + SD / total # of evaluable patients) was achieved in 11/12 (92%).
- All twelve evaluable patients also had > 20%; and 11/12 had > 50% decreases from baseline in CA19.9 levels (a predictive biomarker for long-term outcome and treatment response in pancreatic cancer).

Data have been submitted to the 2015 Gastrointestinal Cancers Symposium for consideration.

"Necuparanib continues to be a promising compound with several potential and relevant mechanisms of action in pancreatic cancer, a field with limited treatment options. Based on the favorable tolerability and encouraging early signals of potential efficacy observed to date, I look forward to further exploring necuparanib in the Part B portion of the Phase 1/2 study," said David Ryan, M.D., Chief of Hematology and Oncology and Clinical Director of the Tucker Gosnell Center for Gastrointestinal Cancers at Massachusetts General Hospital, and Lead Investigator in the trial.

"We are pleased to have achieved a dose of necuparanib in Part A that is significantly higher than the doses of low molecular weight heparins historically tested in studies conducted to evaluate the effect of heparins on survival in patients with cancer," said Jim Roach, M.D., Chief Medical Officer of Momenta Pharmaceuticals. "We are eager to begin dosing patients in the next few weeks in the Part B portion of the study. Furthermore, we look forward to presenting and publishing data from the Part A study regarding safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy over the next several months."

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. 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 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.

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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 timing for clinical development of necuparanib and publication of clinical trial results. 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 June 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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