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First Patient Dosed With M402 in Phase 1/2 Clinical Trial in Metastatic Pancreatic Cancer

Dosing of First Patient Represents Important Milestone in Expanding Pipeline of Novel Oncology Drug Candidates

CAMBRIDGE, Mass., July 2, 2012 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA), a biotechnology company specializing in the characterization and engineering of complex drugs, today announced that dosing has begun in the Phase 1/2 proof-of-concept clinical trial of M402 in combination with gemcitabine in patients with advanced metastatic pancreatic cancer.

M402 is a novel heparan sulfate mimetic that binds to multiple growth factors, adhesion molecules and chemokines to inhibit tumor angiogenesis, progression, and metastasis. The use of heparins to treat venous thrombosis in cancer patients has generated numerous reports of antitumor activity; however, the dose of these drugs has been limited by their anticoagulant activity. M402, which is derived from unfractionated heparin, has been engineered to have significantly reduced anticoagulant activity while preserving the relevant antitumor properties of heparin. Ideally, higher doses of M402 could potentially be administered to further enhance these antitumor properties.

"We developed M402 leveraging our expertise in heparin sulfate proteoglycans (or HSPGs) and their relationship to tumor growth," said Jim Roach, M.D., Momenta's Senior Vice President and Chief Medical Officer. "The M402 clinical trial further demonstrates our ability to understand the structure and biology of complex therapeutics and to engineer a drug that can potentially affect multiple targets involved in the pathogenesis of a broad range of cancers."

"Numerous lines of evidence support the ability of HSPGs to intercept several key contributors to tumor growth," said Keith Flaherty, M.D., Director of Developmental Therapeutics, Cancer Center, Massachusetts General Hospital. "M402 appears to be an advance over other heparins, having been engineered to maximize the antitumor activities of this class."

"Pancreatic cancer has a particularly poor prognosis, given that it is often fairly advanced by the time these patients begin showing symptoms," said David Ryan, M.D., Clinical Director of the Tucker Gosnell Center for Gastrointestinal Cancers at Massachusetts General Hospital, and Lead Principal Investigator for the M402 pancreatic cancer development program. "Furthermore, there are limited treatment options that offer only modest survival benefits. We are eager to evaluate whether M402 can extend the efficacy of gemcitabine in this patient population and look forward to seeing the Phase 1 clinical results next year."

Trial Design

The Phase 1/2 trial is designed to evaluate the safety, efficacy, pharmacokinetics, and pharmacodynamics of M402 in combination with gemcitabine, a first-line standard of care chemotherapy for advanced pancreatic cancer. The Phase 1/2 trial is a two-part study that will enroll approximately 150 patients. Part A is an open-label, multiple ascending dose study. The primary objectives of Part A are to evaluate the safety and tolerability of M402 in combination with gemcitabine and to establish the dose of M402 to take forward into Part B. Data from Part A are expected in the first half of 2013. Pending successful completion of this phase, Momenta expects to initiate Part B of the trial, which will be a randomized, controlled study investigating the safety and antitumor activity of M402 administered in combination with gemcitabine compared with gemcitabine alone.

About M402

M402 is a novel heparan sulfate mimetic with potentially broad anti-angiogenic, anti-proliferative and anti-metastatic properties. Data from multiple preclinical studies have shown that M402 inhibits angiogenesis and tumor progression and metastasis by modulating a variety of growth factors. A preclinical study in a pancreatic cancer model was conducted in collaboration with the Cancer Research Institute (Cambridge, UK). The study showed that M402, in combination with gemcitabine, significantly improved survival and substantially lowered the incidence of metastasis compared with groups treated with gemcitabine alone. M402 has the potential to complement conventional chemotherapy, and as M402 has the ability to bind to multiple heparin binding factors, it may play a role in a broad range of cancers.

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 drug products, as well as to the discovery and development of novel drugs.

To receive additional information about Momenta, please visit the website at www.momentapharma.com, which does not form a part of this press release.

Special Note Regarding Forward-Looking Statements

Statements in this press release regarding management's future expectations, beliefs, intentions, goals, strategies, plans or prospects, including statements relating to the clinical and efficacy potential of M402, are 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, 2012 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.

CONTACT: Investor Contact:

Lora Pike

Momenta Pharmaceuticals

lpike@momentapharma.com

617-395-5189

Source: Momenta Pharmaceuticals