



## **Momenta Pharmaceuticals Announces Results From a Phase 1 Study of M118 Administered as a Subcutaneous Injection**

### **Findings Presented At IXth World Conference On Clinical Pharmacology and Therapeutics Meeting**

CAMBRIDGE, Mass., Jul 29, 2008 (PrimeNewswire via COMTEX News Network) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA), a biotechnology company specializing in the characterization and engineering of complex drugs, today will present safety and tolerability results from a Phase I study of M118, its rationally engineered anticoagulant, in a poster presentation at the IXth World Conference on Clinical Pharmacology and Therapeutics Meeting. The poster, titled "Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of M118, a Novel Rationally Engineered Low Molecular Weight Heparin Given as a Subcutaneous Injection in a Rising Dose Cohort Regimen in Healthy Subjects," reported that M118 was well-tolerated when administered to 36 subjects as a single-dose subcutaneous injection of up to 150 IU/kg (the highest dose evaluated). M118 is being developed as adjunctive pharmacotherapy to treat patients diagnosed with Acute Coronary Syndromes (ACS).

"We are very pleased to report additional data from our phase 1 clinical development program, including the first presentation of data from a study in which M118 was administered subcutaneously. We continue to be encouraged by the potential of M118 as an anticoagulant therapy in ACS," stated Jim Roach, M.D., Chief Medical Officer at Momenta.

The study was a Phase I, single-center, randomized, double-blind, placebo-controlled, single dose escalation study following subcutaneous administration of M118. The primary objective of this study was to evaluate the safety and tolerability of M118 in a rising dose cohort regimen in healthy male subjects, and the secondary objective was to gain information about the pharmacokinetics (PK) and pharmacodynamics (PD). 36 healthy adult male volunteers between 21 and 48 years of age participated in the study; 6 subjects per cohort (4 active and 2 placebo) received a single SC dose of either 25.0, 50.0, 75.0, 100.0, 125 or 150 anti-Factor Xa IU/kg of M118 or placebo (0.9% sterile saline for injection, USP), along with corresponding doses of anti-Factor IIa (17.05, 34.10, 51.15, 68.20, 85.25, and 102.3 anti-Factor IIa IU/kg).

Activated Clotting Time (ACT) and Activated Partial Thromboplastin Time (APTT) were used as point-of-care monitoring of anticoagulation activity following the subcutaneous administration of M118. These PD measures cannot be used to monitor the effects of other low molecular weight heparin products following SC administration. Plasma anti-Factor Xa and anti-Factor IIa activities were found to be highly correlated to the ACT levels following SC dose of M118 at the 75, 100, 125 and 150 IU/kg dose-levels. Significant increases in ACT levels were observed for dose- groups 125 and 150 IU/kg, and the maximum ACT change from baseline was observed in the 125 IU/kg (38.3 seconds +/- 25.3) and 150 IU/kg (41.0 seconds +/- 2.71) dosing groups compared to the placebo treatment. Increases in APTT values and duration of the increase appeared to be dose-related. APTT values returned within the normal range by 12 hours post-dose. Mean APTT values at the 25 IU/kg dose level were comparable to the placebo group and were within the normal range of 25.2-36.0 seconds. No severe or serious adverse events occurred.

These results indicate that standard point-of-care PD markers can be used to monitor the level of anticoagulation provided by M118 following SC administration, and support the continued clinical development of subcutaneously administered M118.

#### **About M118**

M118 is a novel drug candidate that has been rationally engineered using Momenta's proprietary technology and analytical methods to provide anticoagulant therapy to patients with ACS. M118 is designed to interact at multiple points in the coagulation cascade by selectively binding to anti-thrombin III and thrombin, two critical factors in the formation of clots. In preclinical and Phase 1 studies, data have shown that M118 is a potent inhibitor of multiple factors in the blood that lead to clot formation, its effects can be reversed or neutralized and its activity can be monitored. An anticoagulant possessing these properties has the potential to satisfy a currently unmet medical need within the ACS patient population.

#### **About Acute Coronary Syndromes**

ACS is characteristically used to describe patients experiencing an acute myocardial infarction, or heart attack, as well as patients who present at hospitals with unstable angina, a transient blockage of a coronary artery. According to the National Hospital Discharge Survey, each year in the United States there are more than 1.5 million occurrences of either unstable

angina or myocardial infarction requiring medical treatment. As part of the treatment of ACS, anticoagulant agents are routinely administered to prevent the accumulation and formation of blood clots which can lead to serious, life-threatening complications.

## About Momenta

Momenta Pharmaceuticals is a biotechnology company specializing in the detailed structural analysis of complex mixture drugs. 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. Momenta was founded in 2001 based on technology initially developed at Massachusetts Institute of Technology and is headquartered in Cambridge, MA.

## Forward-Looking Statements

Statements in this press release regarding the Company's future expectations, beliefs, intentions, goals, strategies, plans or prospects, including statements relating to the design, development, administration and application of the M118 product candidate or the potential for the Company to demonstrate through preclinical and clinical studies that M118 is safe and tolerable, may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Momenta's actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including those factors contained in Momenta's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008 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. Forward-looking statements include statements regarding Momenta's expectations, beliefs, intentions or strategies regarding the future and can be identified by forward-looking words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "should," "will," and "would" or similar words. Momenta assumes no obligations to update the information included in this press release.

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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