November 1, 2017

Momenta and Mylan Report Initial Results from Phase 1 Clinical Trial for M834, a Proposed Biosimilar of ORENCIA® (abatacept)

CAMBRIDGE, Mass. and HERTFORDSHIRE, United Kingdom and PITTSBURGH, Nov. 01, 2017 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) and Mylan N.V. (NASDAQ:MYL) (TASE:MYL), today announced that M834, a proposed biosimilar of ORENCIA (abatacept), did not meet its primary pharmacokinetic (PK) endpoints in the Phase 1 study to compare the pharmacokinetics, safety and immunogenicity of M834 to US- and EU-sourced ORENCIA in normal healthy volunteers. Momenta and Mylan continue to gather and analyze these data to inform next steps for the program.

"This was an unexpected result and we are disappointed with the outcome of this PK study," said Craig Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "We are in the process of gathering the full data set and will work with Mylan to fully analyze these data to better understand the study results and evaluate next steps for this program. We remain committed to executing on our biosimilar portfolio."

The Phase 1 study was a randomized, double-blind, three-arm, parallel group, single-dose subcutaneous administration clinical study to compare the pharmacokinetics, safety, and immunogenicity of M834, US-sourced ORENCIA, and EU-sourced ORENCIA in 243 normal healthy volunteers.

About M834, a proposed biosimilar of ORENCIA® (abatacept)

M834 is part of the collaboration between Mylan N.V. and Momenta Pharmaceuticals. ORENCIA is a fusion protein and the only CTLA-4Ig approved in the US, EU, and Japan for the treatment of Rheumatoid Arthritis and in the US and EU for the treatment of Psoriatic Arthritis and Juvenile Idiopathic Arthritis. In 2016, worldwide sales of ORENCIA totaled $2.4 billion.

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 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.

Forward Looking Statement For Momenta Pharmaceuticals

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 the future development and commercialization plans for M834; and gathering and analyzing the data from the Phase 1 study for M834 and understanding the results thereof. Forward-looking statements may be identified by words and phrases such as "believe," "continue," "expect," "evaluate," "in the process of gathering," "opportunity," "plan," "will" 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 June 30, 2017 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.

About Mylan

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com.

Forward Looking Statement For Mylan

This press release includes statements that constitute "forward-looking statements," including with regard to future development and commercialization plans for M834; and that Momenta and Mylan continue to gather and analyze the data from the Phase 1 study for M834 to inform next steps. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: success of clinical trials and our or our partners' ability to execute on new product opportunities; any regulatory, legal or other impediments to our or our partners' ability to bring products to market; other risks inherent in product development; the scope, timing, and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on our or our partners' businesses; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; the impact of competition; strategies by competitors or other third parties to delay or prevent product introductions; the effect of any changes in our or our partners' customer and supplier relationships and customer purchasing patterns; any other changes in third-party relationships; changes in the economic and financial conditions of the businesses of Mylan or its partners; uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.

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