November 2, 2016

Momenta and Mylan Initiate Phase 1 Clinical Trial for M834, a Proposed Biosimilar of ORENCIA® (abatacept)

-- Advancement of M834 to clinical-stage development represents important milestone in the Momenta/Mylan biosimilar portfolio --

CAMBRIDGE, Mass. and HERTFORDSHIRE, England and PITTSBURGH, Nov. 2, 2016 /PRNewswire/ -- Momenta Pharmaceuticals, Inc. (Nasdaq: MNTA) and Mylan N.V. (NASDAQ, TASE: MYL), today announced that dosing has begun in a Phase 1 study to compare the pharmacokinetics, safety and immunogenicity of M834, a proposed biosimilar of ORENCIA (abatacept), to US- and EU-sourced ORENCIA in normal healthy volunteers. Under the Momenta-Mylan collaboration agreement, Momenta has achieved the milestone necessary to earn a $25 million payment from Mylan.

"We are deeply committed to expanding treatment access and providing high-quality and affordable biosimilar options for patients who suffer from autoimmune and inflammatory diseases," said Craig Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "Our collaboration with Mylan, one of the largest generics and specialty pharmaceutical companies in the world, positions us to advance this important biosimilar candidate through the clinic. We believe we have the opportunity to be the leader in offering patients a biosimilar version of ORENCIA."

Mylan President Rajiv Malik commented, "Our pipeline of biosimilar products, which is one of the largest in development in the industry, continues to make exciting advancements and today's milestone for M834 is yet another example of this progress. Our partnership with Momenta is based not only on a shared commitment to bringing more affordable versions of critical biologic products to patients around the world, but also on our mutual passion for science and R&D, and our willingness to invest in it. To date, Mylan has invested more than $1 billion in our biologics and insulin analog programs."

The Phase 1 study is a randomized, double-blind, three-arm, parallel group, single-dose study that is expected to enroll approximately 300 healthy volunteers. The companies plan to report top-line data from this study by the end of 2017.

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

M834 is developed in collaboration by 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 the US and EU for the treatment of Juvenile Idiopathic Arthritis. In 2015, worldwide sales of ORENCIA totaled $1.9 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 indications for which M834 may be approved and marketed; the cost-effectiveness and quality of our biosimilars, including M834; the market potential for M834; the timing of commercial launch of M834; the competitive landscape of M834; and the timing of availability of clinical trial results. Forward-looking statements may be identified by words such as "believe," "opportunity," ""plan," "target" 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, 2016 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 2,700 generic and branded pharmaceuticals, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS worldwide depend. We market our products in more than 165 countries and territories. Our global R&D and manufacturing platform includes more than 50 facilities, and we are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 40,000-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 N.V.

This press release includes statements that constitute "forward looking statements," including with respect to Mylan's pipeline; future plans and intentions; biosimilar and insulin programs; and expected timing for reporting on study results. 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: any changes in or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring product candidates to market; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; other 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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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/momenta-and-mylan-initiate-phase-1-clinical-trial-for-m834-a-proposed-biosimilar-of-orencia-abatacept-300355762.html

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