Momenta and Mylan Announce Development Strategy for M710, a Proposed Biosimilar to EYLEA® (aflibercept)

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Targeting the initiation of a pivotal patient clinical trial in the first half of 2018

CAMBRIDGE, Mass., HERTFORDSHIRE, United Kingdom and PITTSBURGH, Jan. 03, 2018 (GLOBE NEWSWIRE) -- Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA) and Mylan N.V. (NASDAQ:MYL) (TASE:MYL) today announced the development strategy for M710, a proposed biosimilar to EYLEA® (aflibercept) injection. EYLEA is the market-leading vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy in patients with diabetic macular edema. The companies plan to initiate a pivotal clinical trial in patients in the first half of 2018.

This trial is a randomized, double-blind, active-control, multi-center study in patients with diabetic macular edema to compare the safety, efficacy and immunogenicity of M710 with EYLEA.

“Expanding treatment access and providing high-quality, affordable drugs for patients is a key attribute of our biosimilars business and an important business objective at Momenta. We believe our proposed biosimilar to EYLEA, in collaboration with Mylan, is an attractive program with limited biosimilar competition, which could result in a first to market advantage,” said Craig Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals.

Mylan President Rajiv Malik commented, “Advancing a biosimilar to EYLEA to the clinical trial period in the first half of the year is an exciting milestone in the development of this important product. We are proud of the significant investments we’ve made in building one of the industry’s most robust biosimilar pipelines, and we look forward to being at the forefront of offering patients a more affordable version of this complex product.”

About M710, a proposed biosimilar of EYLEA® (aflibercept)

M710 is developed in collaboration by Mylan N.V. and Momenta Pharmaceuticals. EYLEA is the market-leading vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of neovascular (wet) age-related macular degeneration , diabetic macular edema , macular edema following retinal vein occlusion and diabetic retinopathy in patients with DME. In 2016, global net sales of EYLEA were $5.2 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 M710 may be approved and marketed; the cost-effectiveness and quality of our biosimilars, including M710; the market potential for M710; the timing of approval or commercial launch of M710; the competitive landscape of M710; and the timing of availability of clinical trial results. Forward-looking statements may be identified by words such as "believe," “could,” “objective”, “opportunity,” ““plan,” “strategy,” “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 September 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 more than 40% of people being treated for HIV/AIDS globally 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. We routinely post information that may be important to investors on our website at investor.mylan.com.

Forward Looking Statement for Mylan N.V.

This press release includes statements that constitute "forward-looking statements," including with regard to: targeting the initiation of a pivotal clinical trial in patients in the first half of 2018; the proposed biosimilar to EYLEA being an attractive program with limited biosimilar competition, which could result in a first to

market advantage; advancing a biosimilar to EYLEA to the clinical trial period in the first half of the year being an exciting milestone in the development of this important product; and looking forward to being at the forefront of offering patients more affordable versions of these complex products. 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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