Mylan to Leverage its World-Class Scientific Platform to Develop a Novel Delivery for Meloxicam, a Non-Opioid Pain Medication

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Mylan acquires global development and marketing rights from Prayog Labs
Once approved, the product could potentially offer a fast-acting, non-addictive treatment for acute pain

HERTFORDSHIRE, England and PITTSBURGH, April 11, 2018 /PRNewswire/ -- Global pharmaceutical company Mylan N.V. (NASDAQ: MYL) today announced that it has acquired global development and marketing rights from Prayog Labs LLC to bring to market a fast-acting Meloxicam as a proposed non-narcotic analgesic. This novel delivery has the potential to provide a non-addictive treatment option for acute pain that patients may experience, for example, during dentistry procedures, post-surgery and with orthopedic defects. Meloxicam also is proposed to treat chronic pain.

In October 2017, the U.S. Department of Health and Human Services declared a nationwide public health emergency regarding the opioid crisis, serving as a rallying cry for affected families, communities, advocacy groups, healthcare professionals, policymakers and the entire healthcare industry to come together to address a serious epidemic debilitating the country. Mylan plays a very small role in the manufacture and sale of opioid products, but the company is committed to being a part of the long-term solution. Promoting the development of non-opioid pain treatments is one of the many tactics the U.S. Food and Drug Administration is focused on as part of its efforts to address this growing public health problem.

Mylan CEO Heather Bresch commented, "We recognize the severity of the opioid crisis as a nationwide public health issue and are committed to doing our part to help in the fight against opioid addiction, abuse and misuse. Offering an alternate, non-opioid pain treatment option represents at least a step toward addressing this national health crisis. Over the course of our almost 60-year history, we have leveraged our expansive scientific capabilities on multiple occasions to help address some of the world's toughest public health issues. We look forward to bringing a novel delivery form of Meloxicam to market for healthcare providers, patients and the public at-large who are affected by this epidemic."

Prayog Labs has completed the initial active pharmaceutical ingredient and formulation development, as well as a pharmacodynamic and preclinical evaluation. Mylan will be submitting an investigational new drug application to the U.S. Food and Drug Administration and plans to use the 505(b)(2) regulatory pathway for product approval.

Mylan President Rajiv Malik added, "At Mylan, part of being built to last is finding the right technologies that can advance our mission to deliver better health for a better world. This novel delivery form of Meloxicam is particularly significant because it could play an important role in addressing a public health crisis. Adding a fast-acting Meloxicam to our pipeline is meaningful not because it will be a key growth driver, but because it's the right thing to do."

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 approximately 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

This press release includes statements that constitute "forward-looking statements", including with regard to: Mylan leveraging its world-class scientific platform to develop a novel delivery for Meloxicam, a non-opioid pain medication; that once approved, the product could potentially offer a fast-acting, non-addictive treatment for acute pain; that we look forward to bringing a novel delivery form of Meloxicam to market for healthcare providers, patients and the public at-large who are affected by this epidemic; that Mylan will be submitting an investigational new drug application to the U.S. Food and Drug Administration and plans to use the 505(b)(2) regulatory pathway for product approval; that the novel, delivery of Meloxicam is particularly significant, because it could play an important role in addressing a public health crisis. 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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Christine Waller (Media), 724.514.1968; Melissa Trombetta (Investors), 724.514.1813