Mylan Statement in Response to FDA Warning Letter Relating to Morgantown Plant

November 20, 2018

HERTFORDSHIRE, England and PITTSBURGH, Nov. 20, 2018 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) today commented on a Warning Letter issued by the U.S. Food and Drug Administration (FDA) on Nov. 9, 2018, relating to its manufacturing facility in Morgantown, West Virginia. This action resulted from previously disclosed observations of the plant made by FDA in April 2018.

As discussed in our second and third quarter earnings calls, we have implemented a comprehensive restructuring and remediation plan at our Morgantown facility. These activities are already reflected in our 2018 outlook, and the issues raised in the Warning Letter are being addressed within the context of this plan. We have been in regular communication with FDA and will continue to work to ensure that the Agency is satisfied with the steps we have taken to resolve all the points raised in the Warning Letter.

The Morgantown facility continues to supply products for the U.S. market while we are executing on our commitments to FDA. We did not expect to have any significant new product launches from the site in 2019. As part of the ongoing restructuring and remediation activities, Mylan has proactively discontinued a number of products from the site while also transferring some products to other sites. These actions have led to a temporary disruption in supply of certain Mylan products for customers. We understand that this current and temporary situation puts a burden on our customers and appreciate their ongoing confidence in Mylan. We will continue to work closely with our customers to mitigate any possible supply disruptions and meet the needs of the patients we serve.

Mylan is committed to maintaining the highest quality manufacturing standards at all of its facilities around the world. We have an industry-leading track record in global quality management, and we take very seriously our continued and comprehensive oversight of Mylan's entire manufacturing network. We continuously learn from inspections of our facilities by FDA and other authorities as regulatory expectations continue to evolve. In 2018, global health authorities conducted more than 100 regulatory inspections, including 21 FDA inspections, of our nearly 50 other manufacturing facilities around the world without regulatory action or significant observations. When we have received FDA warning letters in the past we have worked comprehensively and closely with FDA to address the issues raised and each of those prior letters was successfully resolved. The November 9 Morgantown letter is the sole outstanding FDA Warning Letter to Mylan. We will apply the same rigor and focus to our work with FDA regarding its observations of our manufacturing facility in Morgantown, which remains an important part of Mylan's global manufacturing network.

This press release includes statements that constitute "forward-looking statements", including that Mylan will continue to work to ensure that the Agency is satisfied with the steps we have taken to resolve all the points raised in the Warning Letter; and that we will continue to work closely with our customers to mitigate any possible supply disruptions and meet the needs of the patients we serve. 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: the effect of any failure or inability to resolve the points raised by FDA in the warning letter to the satisfaction of FDA, and the timing of any such resolution; 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.

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.

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