August 18, 2015

Mylan Statement in Response to FDA Warning Letter Relating to Certain Agila Facilities

HERTFORDSHIRE, England and PITTSBURGH, Aug. 18, 2015 /PRNewswire/ -- Mylan N.V. (Nasdaq: MYL) today commented on a warning letter issued by the U.S. Food and Drug Administration (FDA) on Aug. 6, 2015, relating to its Agila Specialty Formulation Facility (SFF), Sterile Product Division (SPD), and Onco Therapies Limited (OTL) sites in India. This action follows inspections of the three sites by FDA as much as a year ago, in 2014 and February 2015, which Mylan has disclosed previously.

This Agency action has no material impact on Mylan's business or its previously announced full year earnings guidance.

Mylan CEO Heather Bresch commented, "Since Mylan acquired the Agila injectables businesses in December 2013 to create a leading global injectables platform, we have been taking extensive action to integrate the Agila business into Mylan's One Quality Standard, and to ensure our leading position as a high quality, reliable source of injectables for the long term. As part of this ongoing process, we have a deep and unwavering commitment to quality everywhere we operate. We have been and will continue to work diligently to address all of the FDA's observations and have made important progress."

This press release includes statements that constitute "forward-looking statements," including with regard FDA actions, our Agila injectables business, and our integration, enhancement, and remediation efforts. 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: risks inherent in legal and regulatory processes; uncertainties and matters beyond the control of management; and the other risks detailed in the company's filings with the Securities and Exchange Commission. The company undertakes no obligation to update these statements for revisions or changes after the date of this release.

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 around 1,400 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which nearly 50% of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in about 145 countries and territories. Our workforce of approximately 30,000 people is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.