



Mylan Statement on Warning Letter Issued to Pfizer's EpiPen® Auto-Injector Manufacturing Site

September 8, 2017

HERTFORDSHIRE, England and PITTSBURGH – Sept. 8, 2017 – On Sept. 5, 2017, the U.S. Food and Drug Administration (“FDA”) issued a warning letter to Meridian Medical Technologies, a Pfizer company (together, “Pfizer”) which is the sole manufacturer for Mylan Specialty L.P., a subsidiary of Mylan N.V., of the EpiPen® Auto-Injector, the EpiPen Jr® Auto-Injector and the authorized generic for both the EpiPen® Auto-Injector and the EpiPen Jr® Auto-Injector. The warning letter, which can be accessed at <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm574981.htm>, was issued in connection with FDA's inspection of Pfizer's pharmaceutical manufacturing facility located in Brentwood, Missouri, where the EpiPen® products are manufactured.

Pfizer is continuing to work with the FDA to resolve the points raised in the warning letter regarding Pfizer's manufacturing of the EpiPen® products and Mylan will do whatever it can to support this process. The warning letter does not affect Pfizer's ability to manufacture and supply the EpiPen® products from the Brentwood, Missouri site, and the Company does not currently anticipate any impact on the supply of EpiPen® products based on this warning letter. Mylan is confident in the safety and efficacy of the EpiPen® products being produced at the site.

This information includes statements that constitute “forward-looking statements.” These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and include statements that Mylan will do whatever it can to support the process of resolving the points raised by FDA in the warning letter; and that Mylan does not anticipate any impact on the supply of EpiPen® products based on the warning letter. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to: the effect of any failure or inability on Pfizer's part to resolve the points raised by FDA in the warning letter to the satisfaction of FDA, including seizure and injunction; any further failure by Pfizer to prevent the recurrence of the points raised by FDA in the warning letter; any changes in or difficulties with Mylan's or Pfizer's ability to develop, manufacture, and commercialize EpiPen® products; the effect of any changes in Mylan's or Pfizer's customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; changes in the economic and financial conditions of the businesses of Mylan or its partners; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations in the United States; 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.

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 approximately 50% of people being treated for HIV/AIDS in the developing world 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.