Mylan Statement Regarding Unit 7 Warning Letter

September 1, 2020

Sept. 1, 2020 -- The U.S. Food and Drug Administration (FDA) issued a Warning Letter to Mylan's API manufacturer, Mylan Laboratories Limited – Unit 7, in which no interruption in manufacturing and distribution is anticipated at the site, no significant commercial impact is expected and no significant launches are planned for Unit 7 in 2020.

The concerns cited by the agency were based on an inspection conducted from February 24 to 28, 2020, which placed a primary focus on nitrosamine or any similar impurities. Since last fall, as have others in the industry, we have worked closely with FDA to thoroughly investigate all potential risks associated with inquiries related to nitrosamine impurities. As noted in the Warning Letter, several months prior to the inspection, we put additional controls, corrective actions and improvements in place at the Unit 7 facility to mitigate any perceived risk of product contamination with patient safety as our primary focus. Importantly, extensive testing of APIs manufactured and distributed by the site was performed for the presence of nitrosamine impurities and no evidence of cross contamination was identified.

Mylan's response to the letter will be submitted within the required time period of 15 working days.

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.

Forward-Looking Statement
This statement includes statements that constitute "forward-looking statements," including with regard to the scope of the FDA warning letter; that Mylan's response will be submitted within the required time period of 15 working days; that no evidence of cross contamination was identified; no interruption in manufacturing or distribution is anticipated at Mylan Laboratories Limited, Unit 7, based on the aforementioned FDA Warning Letter; and no significant commercial impact is expected and no significant launches are planned for Unit 7 in 2020. 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 to resolve the points raised by FDA in the warning letter to the satisfaction of FDA, and the timing of any such resolution; the potential widespread and highly uncertain impact of public health outbreaks, epidemics and pandemics, such as the COVID-19 pandemic; any changes in, interruptions to, or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; 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 and abroad; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; risks associated with international operations; 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.