UPDATED – Mylan Statement Regarding Unit 7 Warning Letter

September 4, 2020

Sept. 3, 2020 – As Mylan previously announced, the U.S. Food and Drug Administration (FDA) issued a Warning Letter to one of Mylan's active pharmaceutical ingredient (API) manufacturing sites, Mylan Laboratories Limited – Unit 7 (the "Warning Letter"). Mylan is proud of its industry leading track record in global quality management, and we take very seriously our continued and comprehensive oversight of Mylan's entire manufacturing network, with patient safety as our primary and unwavering focus. Mylan's response to the Warning Letter will be submitted within the required time period of 15 working days from its receipt and will address each of FDA's observations in detail. In the interim, we are highlighting below several facts we view as important to understanding the context for the Warning Letter and the issues underlying it, especially in view of misleading information currently being circulated with respect to the Warning Letter, based in part upon statements in the Warning Letter itself.

- As FDA and other health regulators have noted, nitrosamines are found in many substances. As recently as September 1, 2020, FDA issued a public statement in which it observed that "nitrosamines are everywhere," including in water and foods such as cured and grilled meats, dairy products and vegetables. As FDA has observed, medications that contain nitrosamines below internationally recognized acceptable intake limits are "not expected to have an increased risk of cancer," even for patients who take the drug every day for 70 years. FDA and other regulatory agencies around the world have established acceptable intake levels for nitrosamines. Those thresholds represent the determinations by the FDA and other health authorities that exposure below those levels pose a negligible risk of harm.

- Since regulatory limits for nitrosamine impurities were established for products with the potential for nitrosamine formation, all such batches released and distributed from Unit 7 have complied with the standard.

- Mylan's proactive, voluntary efforts to identify, isolate and eliminate nitrosamine impurities from products made at Unit 7 substantially predate the February 2020 FDA inspection that ultimately led to the Warning Letter. These measures were consistent with corrective actions and improvements at other Mylan manufacturing sites and any suggestion that corrective measures and controls for nitrosamines are not in place at other Mylan facilities is unfounded.

- Well before FDA inspected Unit 7, Mylan proactively identified recovered solvent from the supplier identified in the Warning Letter as a potential source of nitrosamine impurities. Mylan had stopped purchasing recovered solvents from the supplier months prior to FDA's inspection and resulting regulatory action concerning that supplier. The Warning Letter and some follow-on reports incorrectly imply that Mylan continued purchasing recovered solvents from the supplier after regulatory action was taken, which is not true.

- We have been working closely with FDA and other health regulators around the world since the existence of nitrosamine impurities was initially observed in certain APIs at various manufacturers in 2018. Well before FDA inspected Unit 7, Mylan had implemented an array of measures, including completing risk assessments for all APIs produced at Unit 7 and conducting enhanced testing for impurities in API, intermediates, solvents, and raw materials, where appropriate.

- Mylan conducted comprehensive testing on hundreds of batches distributed from Unit 7. Mylan's testing confirmed that any trace amounts of nitrosamines detected in the finished API was consistent with the health and safety limits established by applicable health authorities. Our testing also showed no evidence of cross-contamination from inadequate cleaning. The theoretical possibility of cross-contamination referenced in the Warning Letter and related news reports is conjectural, not a factual determination.

Mylan does not anticipate any interruption in manufacturing at or distribution from Unit 7, nor any significant commercial impact as a result of the Warning Letter. There are no significant launches planned using product manufactured at Unit 7 in 2020 and we do not presently expect any product recalls in connection with the Warning Letter.

Forward-Looking Statements

This statement includes statements that constitute "forward-looking statements," including with regard to the scope of the Warning Letter; that Mylan's response to the Warning Letter will be submitted within the required time period of 15 working days from its receipt and will address each of FDA's observations in detail; that Mylan does not anticipate any interruption in manufacturing at or distribution from Unit 7, nor any significant commercial impact as a result of the Warning Letter; and there are no significant launches planned using product manufactured at Unit 7 in 2020 and we do not presently expect any product recalls in connection with 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 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 other risks described in greater detail in our filings with the Securities and Exchange Commission, including the factors described under "Risk Factors" in Mylan's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other filings. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.