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Mylan Finalizes Settlement Agreement on Medicaid Rebate Classification for EpiPen® Auto-Injector

HERTFORDSHIRE, England and PITTSBURGH, Aug. 17, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced that its subsidiaries, Mylan Inc. and Mylan Specialty L.P., have signed an agreement with the U.S. Department of Justice ("DOJ") and two relators finalizing the Medicaid drug rebate settlement that the Company announced on Oct. 7, 2016 for \$465 million.



The settlement resolves claims relating to the classification of EpiPen® Auto-Injector and EpiPen Jr® Auto-Injector for purposes of the Medicaid Drug Rebate Program. The question in the underlying matter was whether the EpiPen products were properly classified with the Centers for Medicare and Medicaid Services ("CMS") as a non-innovator drug under the applicable definition in the Medicaid Rebate statute and subject to the formula that is used to calculate rebates to Medicaid for such drugs. EpiPen Auto-Injector has been classified with CMS as a non-innovator drug since before Mylan acquired the product in 2007 based on longstanding written guidance from the federal government.

The settlement provides for resolution of all potential Medicaid rebate liability claims by the federal government, as well as potential claims by certain hospitals and other covered entities that participate in the 340B Drug Pricing Program. The settlement allocates money to the Medicaid programs of all 50 states and establishes a framework for resolving all potential state Medicaid rebate liability claims within 60 days. In connection with the settlement, Mylan also has entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services. The settlement does not contain an admission or finding of wrongdoing. Mylan will reclassify EpiPen Auto-Injector for purposes of the Medicaid Drug Rebate Program and pay the rebate applicable to innovator products effective as of April 1, 2017.

Mylan CEO Heather Bresch commented, "As we said when we announced the settlement last year, bringing closure to this matter is the right course of action for Mylan and our stakeholders to allow us to move forward. Over the course of the last year, we have taken significant steps to enhance access to epinephrine auto-injectors, including bringing a solution to the fast-changing healthcare landscape in the U.S. by launching an authorized generic version at less than half the wholesale acquisition cost of the brand and meaningfully expanding our patient access programs. Mylan has always been committed to providing patients in the U.S. and around the world with access to medicine, and we look forward to continuing to deliver on this mission."

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.

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