October 7, 2016

Mylan Agrees to Settlement on Medicaid Rebate Classification for EpiPen® Auto-Injector

Mylan updates full year 2016 earnings guidance
Mylan to report third quarter 2016 financial results on Nov. 9, 2016

WASHINGTON, Oct. 7, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced that its subsidiary, Mylan Inc., has agreed to the terms of a $465 million settlement with the U.S. Department of Justice ("DOJ") and other government agencies that will resolve questions that have been raised about the classification of EpiPen® Auto-Injector and EpiPen Jr® Auto-Injector (collectively, "EpiPen Auto-Injector") for purposes of the Medicaid Drug Rebate Program.

Seeing is believing™

The terms of the settlement do not provide for any finding of wrongdoing on the part of Mylan Inc. or any of its affiliated entities or personnel. The question in the underlying matter was whether EpiPen Auto-Injector was properly classified with the Centers for Medicaid and Medicare 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 terms provide for resolution of all potential rebate liability claims by federal and state governments as to whether the product should have been classified as an innovator drug for CMS purposes and subject to a higher rebate formula. In connection with the settlement, Mylan expects to enter into a corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services. Mylan will continue to work with the government to finalize the settlement.

Mylan CEO Heather Bresch commented, "This agreement is another important step in Mylan's efforts to move forward and bring resolution to all EpiPen Auto-Injector related matters. The agreement is in addition to the significant steps Mylan has taken in relation to EpiPen Auto-Injector over the past several weeks, including the unprecedented, pending launch of a generic version of EpiPen Auto-Injector and expansion of our patient access programs for this product. Entering into this settlement is the right course of action at this time for the Company, its stakeholders and the Medicaid program."

Mylan will include a pre-tax charge of approximately $465 million in the quarter ended Sept. 30, 2016 as a result of this settlement.

2016 Earnings Guidance Update

Mylan also announced it expects full year 2016 adjusted diluted earnings per ordinary share ("EPS") to be between $4.70 - $4.90, as compared to the previously communicated full year guidance range of $4.85 - $5.15. The majority of this change in full year 2016 adjusted EPS guidance is the result of the previously announced changes in EpiPen Auto-Injector access programs and the upcoming launch of the generic to EpiPen Auto-Injector. These initiatives seek to further enhance access to, and affordability of, EpiPen Auto-Injector. Much of the impact of this guidance change will occur in the third quarter.

Mylan remains committed to its target of at least $6.00 in adjusted EPS in 2018.

Mylan is not providing forward looking guidance for full year 2016 U.S. GAAP EPS guidance or a reconciliation of full year

2016 adjusted EPS to U.S. GAAP EPS because Mylan is unable to predict with reasonable certainty the ultimate outcome of certain significant items without unreasonable effort. These items include, but are not limited to, acquisition-related expenses including those related to the recently closed Meda transaction, restructuring expenses, asset impairments, litigation settlements, changes to contingent consideration and certain other gains or losses. These items are uncertain, depend on various factors, and could have a material impact on U.S. GAAP EPS for the guidance period.

Mylan to Report Third Quarter 2016 Financial Results on Nov. 9, 2016

Mylan will host a conference call and live webcast, on Wednesday, Nov. 9, 2016 at 4:30 p.m. ET, to review the Company's financial results for the third quarter ended Sept. 30, 2016. Mylan will release its financial results on Nov. 9 after the close of the U.S. financial markets.

The dial-in number to access the earnings call is 800.514.4861 or 678.809.2405 for international callers. To access the live webcast, please log on to Mylan's website, mylan.com, at least 15 minutes before the event is scheduled to begin to register and download or install any necessary software. A replay of the webcast will be available at mylan.com/investors, for a limited time.

Mylan now intends to hold its investor day in conjunction with the release of its fourth quarter results.

Forward-Looking Statements

This press release includes statements that constitute "forward-looking statements," including with regard to the agreement on terms of a settlement and the expected payment, the full year 2016 adjusted EPS guidance and Mylan's commitment to its target of at least $6.00 in adjusted EPS in 2018. 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: the inability or unwillingness on the part of any of the parties to agree to a final settlement; any legal or regulatory challenges to the settlement; any failure by third parties to comply with their contractual obligations; any changes in or difficulties with our inventory of, and our ability to manufacture and distribute, the EpiPen® Auto-Injector; the potential impact of any change in patient access and the introduction of a generic version of the EpiPen Auto-Injector; the effect of any changes in our customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the possibility that Mylan may be unable to achieve expected synergies and operating efficiencies in connection with Mylan's acquisition of Meda AB (publ.) ("Meda") by Mylan within the expected time-frames or at all and to successfully integrate Meda; the impact of competition; changes in the economic and financial conditions of the businesses of the Company; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on our business; any regulatory, legal, or other impediments to our ability to bring our 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; our ability to protect our intellectual property and preserve intellectual property rights; expected or targeted future financial and operating performance and results; inherent uncertainties involved in the estimates and judgments used in the preparation of financial statements, and the providing of estimates of financial measures, in accordance with U.S. GAAP and related standards or on an adjusted basis; other uncertainties and matters beyond the control of management; and the other risks detailed in the Company'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.

Non-GAAP Financial Measures: Full year 2016 adjusted EPS guidance and target of at least $6.00 in adjusted EPS in 2018

This press release includes the presentation and discussion of certain financial information that differs from what is reported under accounting principles generally accepted in the United States ("U.S. GAAP"). Adjusted EPS is a non-GAAP financial measure calculated as U.S. GAAP EPS, adjusted for various items, including acquisition related amortization; litigation settlements, net; non-cash accretion of contingent consideration liability; certain R&D milestone payments; clean energy investments pre-tax losses; acquisition related costs; restructuring and other special items; and the tax effect of these items. This non-GAAP financial measure is presented in order to supplement investors' and other readers' understanding and assessment of the financial performance of Mylan N.V. ("Mylan" or the "Company"). Management uses this measure internally for forecasting, budgeting, measuring its operating performance, and incentive-based awards. Mylan believes that this non-GAAP financial measure is useful supplemental information for its investors and when considered together with its U.S. GAAP financial measure and the reconciliation to the most directly comparable U.S. GAAP financial measure, provides a more complete understanding of the factors and trends affecting its operations. The financial performance of the Company is measured by senior management, in part, using adjusted EPS, along with other performance metrics. Management's annual incentive compensation is derived, in part, based on the adjusted EPS metric. In addition, primarily due to acquisitions, Mylan believes that an evaluation of its ongoing operations (and comparisons of its current operations with historical and future operations) would be difficult if the disclosure of its financial results were limited to financial measures prepared only in accordance with U.S. GAAP. Investors and other readers should consider non-GAAP measures

only as supplements to, not as substitutes for or as superior measures to, the measures of financial performance prepared in accordance with U.S. GAAP. For additional information regarding the components and uses of non-GAAP financial measures refer to Management's Discussion and Analysis of Financial Condition and Results of Operations-- Use of Non-GAAP Financial Measures section of Mylan's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016. With respect to the target of at least $6.00 in adjusted EPS in 2018, the Company is not providing a U.S. GAAP target or reconciliation because the Company has not quantified all future amounts, including U.S. GAAP amounts, related to this target and it does not represent Company guidance.

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 2,700 generic and branded pharmaceuticals, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS worldwide depend. We market our products in more than 165 countries and territories. Our global R&D and manufacturing platform includes more than 50 facilities, and we are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 40,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

Logo - http://photos.prnewswire.com/prnh/20140423/77793