February 19, 2016

Mylan's ANDA for Generic Advair Diskus® Accepted for Filing by FDA

FDA Provides GDUFA Goal Date of March 28, 2017

HERTFORDSHIRE, England, and PITTSBURGH, Feb. 19, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced that its abbreviated new drug application (ANDA) for fluticasone propionate 100, 250, 500 mcg and salmeterol 50 mcg inhalation powder has been accepted for filing by the U.S. Food and Drug Administration (FDA). The FDA provided Mylan a GDUFA goal date of March 28, 2017. This product is the generic version of GlaxoSmithKline's Advair Diskus®, which is indicated for the treatment of asthma and the maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD).

Mylan CEO Heather Bresch said, "The FDA's acceptance of our ANDA filing is an important achievement for our generic Advair Diskus development program and our respiratory franchise as a whole. Leading up to this milestone, we held several discussions with FDA to provide input on and solidify our understanding of the agency's expectations for the development of the first AB-rated generic Advair Diskus product. Our ongoing dialogue with FDA and this ANDA filing acceptance gives us further confidence in the robustness of our clinical program and reinforces our continued belief that Mylan will be the first to bring to market an AB-rated, substitutable generic form of Advair Diskus."

Mylan President Rajiv Malik added, "The acceptance of our generic Advair Diskus ANDA filing demonstrates, yet again, Mylan's leadership in bringing high quality, affordable medicine to patients. I would like to thank our generic Advair team around the world, especially our teams in the U.K. and Ireland. We look forward to now working with FDA through the approval process to bring this very important product to patients."

Advair Diskus had U.S. sales of approximately $4.8 billion for the 12 months ending Dec. 31, 2015, according to IMS Health.

Currently, Mylan has 264 ANDAs pending FDA approval representing $102.3 billion in annual brand sales, according to IMS Health. Forty-eight of these pending ANDAs are potential first-to-file opportunities, representing $35.4 billion in annual brand sales, for the 12 months ending June 30, 2015, according to IMS Health.

About Mylan
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 1,400 generic and branded pharmaceuticals, including antiretroviral therapies on which nearly 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in approximately 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 nearly 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

This press release includes statements that constitute "forward-looking statements," including with regard to the GDUFA goal date; Mylan's ongoing dialogue with FDA and this ANDA filing acceptance giving Mylan further confidence in the robustness of its clinical program and reinforces our continued belief that Mylan will be the first to bring to market an AB-rated, substitutable generic form of Advair Diskus; Mylan leading the way in bringing high quality, affordable medicine to patients; bringing the product to market; and working with FDA on the next phase of the approval process. 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: strategies by competitors or other third parties to delay or prevent product introductions; the effect of any changes in our 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; 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; 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. The company undertakes no obligation to update these statements for revisions or changes after the date of this release.

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