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Mylan Confirms FDA Submission of ANDA for Generic Advair Diskus®

HERTFORDSHIRE, England and PITTSBURGH, Jan. 11, 2016 /PRNewswire/ -- In advance of its upcoming presentation at the J.P. Morgan Annual Healthcare Conference tomorrow, Mylan N.V. (NASDAQ, TASE: MYL) today confirmed that it submitted its abbreviated new drug application (ANDA) for fluticasone propionate 100, 250, 500 mcg and salmeterol 50 mcg inhalation powder to the U.S. Food and Drug Administration (FDA) in Dec. 2015. 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 will provide appropriate updates as the FDA process unfolds.Â

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 more than 30,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

Advair® is a registered trademark of GlaxoSmithKline.

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