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Mylan Comments on Generic Advair Diskus® Abbreviated New Drug Application

HERTFORDSHIRE, England and PITTSBURGH, March 29, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today commented on the status of its abbreviated new drug application (ANDA) with the U.S. Food and Drug Administration (FDA) for its generic version of GlaxoSmithKline's Advair Diskus®.

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In conjunction with Mylan's GDUFA goal date, the company received a complete response letter from FDA regarding its ANDA for generic Advair Diskus®. Mylan is in the process of reviewing this response and will provide an update on its application as soon as practicable once it has completed its review and discussed the FDA's feedback with the agency.

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 market a growing portfolio of approximately 7,500 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.