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Mylan Commences Phase III Clinical Trials for its Generic Version of Advair Diskus® and Insulin Analog to Lantus®

Clinical Trials Mark Important Milestone in Development of Two Highly Complex Products

PITTSBURGH, Sept. 16, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL), one of the world's leading global pharmaceutical companies, today announced it is initiating Phase III clinical trials for its generic version of GlaxoSmithKline's Advair Diskus® and its insulin analog to Sanofi's Lantus®.

In October 2014, Mylan will commence a Phase III clinical trial to evaluate the equivalence of its product to Advair Diskus when administered by inhalation in adult asthma patients.



Two Phase III clinical trials for Mylan's insulin analog program already are underway. In August 2014, the company initiated INSTRIDE 1 and INSTRIDE 2 to compare the efficacy and safety of Mylan's insulin Glargine with that of Lantus® in both Type 1 and Type 2 diabetes mellitus patients.

Mylan CEO Heather Bresch said, "The commencement of Phase III clinical trials for Mylan's generic Advair Diskus® and insulin Glargine programs are important milestones in the progress of two of our strategic growth drivers, demonstrating our strong capabilities in developing complex, difficult-to-manufacture products. We look forward to providing patients with access to high quality, more affordable versions of these medications upon final FDA approval."

Mylan President Rajiv Malik added, "These noteworthy clinical trial developments, combined with the significant strides we have made in advancing our production scale manufacturing, reinforce our continued belief that Mylan will be the first to bring to market an AB-rated, substitutable generic form of Advair Diskus and one of the first to bring to market an interchangeable insulin analog to Lantus. These products, in addition to the hundreds of others in our pipeline, will continue to expand and diversify our portfolio and further differentiate Mylan with its customers."

About Generic Advair Diskus Trial

The clinical trial is a randomized, double-blind, double dummy, parallel group study to determine the local equivalence of multiple doses of Mylan's generic product to Advair Diskus when administered via oral inhalation in adult asthma patients. The primary endpoint of the study is the FEV1 area under the effect curve, which is the volume of air that has been forcibly exhaled in one second, after full inspiration. The study also will examine adverse events and device usability. The study is expected to commence in October 2014 and be completed in April 2015. More information about the trial will be available at clinicaltrials.gov.

About INSTRIDE 1 and INSTRIDE 2 Trials

INSTRIDE 1 and INSTRIDE 2 are open-label, randomized, multicenter, parallel-group clinical trials

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comparing the efficacy and safety of Mylan's insulin Glargine with that of Lantus® in Type 1 and Type 2 diabetes mellitus patients, respectively. The purpose of both studies is to test whether Mylan's insulin Glargine once daily is non-inferior to Lantus® once daily when administered in combination with other anti-diabetic drugs. Both studies commenced in August 2014 and are expected to be completed in June 2016. More information about [INSTRIDE 1](#) and [INSTRIDE 2](#) is available at clinicaltrials.gov.

This press release includes statements that constitute "forward-looking statements," including with regard to sales of products and the company's strategy, future growth and performance. 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 impacts of competition; changes in economic and financial conditions of the company's business; strategies by competitors or other third parties to delay or prevent product introductions; risks inherent in legal and regulatory processes; 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.

Mylan is a global pharmaceutical company committed to setting new standards in health care. 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 1,300 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately 40% of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in approximately 140 countries and territories. Our workforce of more than 20,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. But don't take our word for it. See for yourself. See inside. mylan.com

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