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Mylan Announces the U.S. Patent and Trademark Appeal Board Institutes Inter Partes Review Proceedings on All Claims Against Sanofi's Lantus® Patents

HERTFORDSHIRE, England and PITTSBURGH, Dec. 14, 2017 /PRNewswire/ -- [Mylan](#) N.V. (NASDAQ, TASE: MYL) today announced that the U.S. Patent and Trademark Appeal Board (PTAB) has instituted *inter partes* review (IPR) proceedings on all claims against two Orange Book-listed patents, U.S. Patent Nos. 7,476,652 and 7,713,930, owned by Sanofi for Lantus® (insulin glargine injection) 100 Units/mL. Mylan's 505(b)(2) New Drug Application (NDA) for Insulin Glargine in vial and pen dosage forms is under active review with the U.S. Food and Drug Administration. Lantus® and Lantus® Solostar® are prescription medicines indicated for improving glycemic control in adult patients with diabetes mellitus.

Mylan CEO [Heather Bresch](#) commented, "The PTAB's decision to institute IPR proceedings against the two Orange Book-listed patents for Lantus is another step forward in our ongoing efforts to bring an interchangeable insulin glargine to diabetes patients as soon as possible. There are more than 29 million people in the U.S. living with diabetes who deserve access to more affordable treatment options. As a leading producer of oral diabetes medicines, we are deeply committed to this patient community and believe bringing lower-cost alternatives to Lantus and Lantus SoloSTAR will fulfill a critical medical need."

In October, Sanofi initiated patent infringement litigation against Mylan's NDA in the United States District Court for the District of New Jersey that includes these two Lantus patents.

Total IQVIA sales for the 12 months ending Oct. 31, 2017, were approximately \$2.74 billion for Lantus 100 Units/mL and about \$4.98 billion for Lantus SoloSTAR.

This press release includes statements that constitute "forward-looking statements," including with regard to the PTAB's decision to institute IPR proceedings against the two Orange Book-listed patents for Lantus being another step forward in Mylan's ongoing efforts to bring an interchangeable insulin glargine to diabetes patients as soon as possible. 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: any changes in or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; the effect of any changes in Mylan's or its partners' 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 or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; risks associated with international operations; other uncertainties and matters beyond the control of management; and the other risks detailed in Mylan'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.

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 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally 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](#). We routinely post information that may be important to investors on our website at [investor.mylan.com](#).



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