Sanofi's Formulation Patents on Multibillion-Dollar Lantus® are Invalidated by U.S. Patent and Trademark Office via IPR, Announces Mylan

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Mylan achieves key milestone to provide U.S. diabetes patients with more affordable generic version of Sanofi's Lantus® insulin glargine vials

HERTFORDSHIRE, England and PITTSBURGH, Dec. 13, 2018 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) today announced that the U.S. Patent and Trademark Appeal Board (PTAB) has ruled in favor of Mylan in its *inter partes* review (IPR) proceedings and found all claims of Sanofi's Lantus (insulin glargine 100 Units/mL) formulation patents (U.S. Patent Nos. 7,476,652 and 7,713,930) unpatentable. Lantus is a long-acting insulin used to treat adults with type 2 diabetes and adults and pediatric patients with type 1 diabetes for the control of high blood sugar. Sanofi sells the product in vials (Lantus) and as a disposable injection pen (Lantus SoloSTAR®). Mylan's 505(b)(2) New Drug Application (NDA) for generic versions of Lantus and Lantus SoloSTAR, co-developed with Biocon, is under active review by the U.S. Food and Drug Administration.

Mylan CEO Heather Bresch commented, "For years, Mylan has been investing in the development of a more affordable generic to insulin glargine for diabetes patients. The PTAB's favorable ruling that invalidates two Sanofi Lantus® formulation patents is an important step forward in our journey to help address the needs of nearly 30 million Americans living with diabetes. We take seriously the responsibility to improve insulin access and are honored to be a part of the solution that will bring much-needed competition to this critical market."

In October 2017, 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 formulation patents listed as covering Lantus as well as other patents listed as covering the Lantus SoloSTAR injection pen. That litigation is pending, and no trial date has been set.

Sanofi's total IQVIA sales for the 12 months ending Oct. 31, 2018, were approximately $2.14 billion for Lantus 100 Units/mL and about $4.39 billion for Lantus SoloSTAR.

This press release includes statements that constitute "forward-looking statements", including with respect to regulatory review and approval, and the outcome of pending litigation. 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: success of clinical trials and our or our partners' ability to execute on new product opportunities; any regulatory, legal or other impediments to our or our partners' ability to bring products to market; other risks inherent in product development; the scope, timing, and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on our or our partners' businesses; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; the impact of competition; strategies by competitors or other third parties to delay or prevent product introductions; the effect of any changes in our or our partners' customer and supplier relationships and customer purchasing patterns; any other changes in third-party relationships; changes in the economic and financial conditions of the businesses of Mylan or its partners; 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 approximately 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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