Mylan Invalidates Sanofi's Lantus® SoloSTAR® Device Patents in IPR Proceedings

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Mylan prepared to bring its insulin glargine products to market after FDA approval

HERTFORDSHIRE, England and PITTSBURGH, May 29, 2020 /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 inter partes review (IPR) proceedings finding all challenged claims of Sanofi's Lantus® SoloSTAR® device patents, U.S. Patent Nos. 8,603,044, 8,992,486, and 9,526,844 unpatentable. The PTAB found three claims of the 9,604,008 patent unpatentable, and two claims to be patentable. However, Mylan has previously obtained a covenant not to sue from Sanofi on the '008 patent and therefore this ruling does not impact Mylan's ability to launch upon final approval from the U.S. Food and Drug Administration. The PTAB also found Sanofi's proposed amended claims for the '486 and '844 patents unpatentable.

Mylan CEO Heather Bresch commented, "Today's decision by the U.S. Patent and Trademark Appeal Board invalidating Sanofi's Lantus device patents is another significant milestone clearing the pathway for our insulin glargine product Semglee to come to market for the millions of Americans living with diabetes. We're pleased with the PTAB's decision, which will help bring competition to the marketplace and should reduce the cost of this critical medication. Today's decision is likely the final defeat of Sanofi's attempts to prevent generic competition. With this final victory in hand, we now look forward to working with FDA to complete the regulatory review process and introduce Semglee in the U.S. as soon as possible."

Mylan President Rajiv Malik added, "We have always maintained that the science behind this product, and Mylan's overall capabilities in bringing complex, higher value chain products to the market, is a cornerstone of the strength and foundation of the future growth of our company. While we remain on track to launch Semglee following FDA approval, we will continue to explore all pathways of interchangeability for both dosage forms to achieve the broadest level of access possible for patients in the U.S. and around the world."

Last month, the PTAB invalidated the sole challenged claim of another Lantus SoloSTAR device patent, U.S. Patent No. 8,679,069, and, in March, Mylan announced that the U.S. District Court of New Jersey found the asserted claims of the '844 patent not infringed by Mylan's insulin glargine product and invalid for lack of written description. Sanofi's formulation patents (U.S. Patent Nos. 7,476,652 and 7,713,930) were previously affirmed to be invalid by the Federal Circuit. The '844 and '652 patents are the only remaining patents asserted by Sanofi against Mylan's insulin glargine products.

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. Mylan's 505(b)(2) New Drug Application (NDA) is under active review by the U.S. Food and Drug Administration.

Sanofi sells the product in vials (Lantus) and as a disposable injection pen (Lantus SoloSTAR®).

Sanofi's total IQVIA sales for the 12 months ending March 31, 2020, were approximately $1.71 billion for Lantus 100 Units/mL and about $4.32 billion for Lantus SoloSTAR.

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 portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which approximately 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.

Forward-Looking Statements
This press release includes statements that constitute "forward-looking statements," including with regard to the outcome of litigation; the timing of regulatory approvals; that Mylan is prepared to bring its insulin glargine products to market after FDA approval; that Mylan has previously obtained a covenant not to sue from Sanofi on the '008 patent and therefore this ruling does not impact Mylan's ability to launch upon final approval from the U.S. Food and Drug Administration; that today's decision by the U.S. Patent and Trademark Appeal Board invalidating Sanofi's Lantus device patents is another significant milestone clearing the pathway for our insulin glargine product, Semglee™, to come to market for the millions of Americans living with diabetes; Mylan is pleased with the PTAB's decision, which will help bring competition to the marketplace and should reduce the cost of this critical medication; today's decision is likely the final defeat of Sanofi's attempts to prevent generic competition; with this final victory in hand, we now look forward to working with FDA to complete the regulatory review process and introduce Semglee in the U.S. as soon as possible; we have always maintained that the science behind this product, and Mylan's overall capabilities in bringing complex, higher value chain products to the market, is a cornerstone of the strength and foundation of the future growth of our company; and while we remain on track to launch Semglee following FDA approval, we will continue to explore all pathways of interchangeability for both dosage forms to achieve the broadest level of access possible for patients in the U.S. and around the world. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to the potential widespread and highly uncertain impact of public health outbreaks, epidemics and pandemics, such as the COVID-19 pandemic; any changes in, interruptions to, or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; 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; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; 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.

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