Mylan Wins District Court Decision Against Sanofi's Lantus® SoloSTAR® Patent

March 10, 2020

All claims of '844 device patent found invalid and not infringed

HERTFORDSHIRE, England and PITTSBURGH, March 10, 2020 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) today announced that the U.S. District Court of New Jersey found the device patent claims (U.S. Patent No. 9,526,844) asserted by Sanofi against Mylan's insulin glargine product not infringed and invalid for lack of written description. Separately, as previously announced, Sanofi's formulation patents (U.S. Patent No. 7,476,652 and U.S. Patent No. 7,713,930) were previously affirmed to be invalid by the Federal Circuit. The '844 and '652 patents were the only patents being asserted by Sanofi against Mylan's insulin glargine product.

Mylan CEO Heather Bresch commented, "Today's decision by the District Court represents a significant milestone for patient access and Mylan's effort to bring a more affordable insulin glargine to those living with diabetes in the U.S. As the cost of diabetes medications continues to rise, we now are one step closer to being able to meet unmet patient needs through the launch of our Semglee® insulin glargine, pending final approval from the U.S. Food and Drug Administration."

Mylan President Rajiv Malik added, "We are encouraged by today's legal win on Mylan's insulin glargine and remain very confident in the strong science behind the product itself. We believe that this scientific excellence will also be central to our work to bring an interchangeable product option. We look forward to serving patients in the U.S. with the same Semglee® that so many others have come to rely on around the world and adding to our existing offering of oral solid dose medications for those living with diabetes."

Malik continued, "Today's outcome illustrates and further adds to our ability to leverage both our own internal scientific capabilities as well as those of our partners to bring complex, higher value chain products to market, delivering innovation to patients and creating a foundation that will fuel our future growth."

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. The product, co-developed with Biocon, has received regulatory approval in more than 45 countries around the world. Biocon continues to be confident in its ability to achieve facility clearance.

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 Jan. 31, 2020, were approximately $1.73 billion for Lantus 100 Units/mL and approximately $4.24 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 growing 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 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.

This press release includes statements that constitute "forward-looking statements," including with regard to: regulatory review and approval; the outcome of litigation; that today's decision by the District Court represents a significant milestone for patient access and Mylan's effort to bring a more affordable insulin glargine to those living with diabetes in the U.S.; as the cost of diabetes medications continues to rise, we now are one step closer to being able to meet unmet patient needs through the launch of our Semglee® insulin glargine, which we continue to expect to be able to bring to market by the middle of this year pending final approval from the U.S. Food and Drug Administration; that we are encouraged by today's legal win on Mylan's insulin glargine and remain very confident in the strong science behind the product itself; that we believe that this scientific excellence will also be central to our work to bring an interchangeable product option; that today's outcome illustrates and further adds to our ability to leverage both our own internal scientific capabilities as well as those of our partners to bring complex, higher value chain products to market, delivering innovation to patients and creating a foundation that will fuel our future growth; and that Biocon continues to be confident in its ability to achieve facility clearance. 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 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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