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Mylan Announces Global Settlement and License Agreements with Genentech and Roche on Herceptin®

HERTFORDSHIRE, England and PITTSBURGH, March 13, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced that Mylan has agreed to the terms of a global settlement with Genentech, Inc. and F. Hoffmann-La Roche Ltd. in relation to patents for Herceptin® (trastuzumab), which provides Mylan with global licenses for its trastuzumab product.

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The global license will provide a clear pathway for Mylan to commercialize its trastuzumab product in various markets around the world, commencing on the license effective dates, which are confidential. The licenses pertain to all countries except Japan, Brazil and Mexico. In addition to eliminating any legal uncertainty over the launch of Mylan's trastuzumab, the settlement eliminates further patent litigation expenses associated with Genentech and Roche.

Mylan has agreed to withdraw its pending Inter Partes Review (IPR) challenges against two U.S. Genentech patents (patent numbers 6,407,213 and 6,331,415) as part of the settlement.

Following this settlement and the recent acceptance of Mylan's application for its proposed biosimilar trastuzumab with the U.S. Food and Drug Administration (FDA), Mylan anticipates potentially being the first company to launch a biosimilar to Herceptin in the U.S.

All other terms and conditions of the settlement and license agreement are confidential.

Mylan CEO Heather Bresch commented, "There is an unmet need for access to more affordable versions of biologic products such as trastuzumab. We look forward to enhancing access to this important treatment option, which complements our comprehensive cancer care offerings, in the U.S. and around the world. With 16 biosimilar products in development, we believe Mylan has one of the industry's broadest portfolios of biosimilars and that we will be a leader in bringing high-quality biosimilar products to market given our ability not only to develop and manufacture such complex products, but also to navigate the intricate regulatory and legal environment and successfully commercialize these products on a global basis."

Mylan's proposed biosimilar trastuzumab is one of the six biologic products co-developed by Mylan and Biocon for the global marketplace. Mylan has exclusive commercialization rights for the proposed biosimilar trastuzumab in the U.S., Canada, Japan, Australia, New Zealand and in the European Union and European Free Trade Association countries. Biocon has co-exclusive commercialization rights with Mylan for the product in the rest of the world.

In the U.S., Mylan's Biologics License Application (BLA) for proposed biosimilar trastuzumab is currently under review by FDA. The anticipated FDA goal date set under the Biosimilar User Fee Act (BsUFA) is Sept. 3, 2017.

Mylan currently markets its trastuzumab products in 14 emerging markets and has submissions pending in the European Union and several additional emerging markets, in addition to the U.S.

This press release includes statements that constitute "forward-looking statements," including with respect to whether the global license will permit provide a clear pathway for Mylan to commercialize its trastuzumab product in various markets around the world; any legal uncertainty over the launch of Mylan's trastuzumab; whether the settlement will eliminate further patent litigation expenses associated with Genentech and Roche; Mylan's ability to be the first company to launch a

biosimilar to Herceptin in the U.S.; Mylan's ability to enhance access to this important treatment option for patients in the U.S. and around the world; and Mylan's ability to be a leader in bringing high-quality biosimilar products to market. 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: Mylan's ability to realize the anticipated benefits of this legal settlement; any changes in or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize its biosimilar products, including trastuzumab in markets around the world; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring such products to market; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; 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.

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 market a growing portfolio of approximately 7,500 products around the world, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world 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.