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Mylan Expands Access to HIV/AIDS Medicines with Launch of First Generic Sustiva® Tablets

- **Launch further strengthens Mylan's leading antiretroviral portfolio -**
- **Mylan is eligible for 180 days of exclusivity -**

HERTFORDSHIRE, England and PITTSBURGH, Feb. 1, 2018 /PRNewswire/ -- Global pharmaceutical leader [Mylan](#) N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Efavirenz Tablets USP, 600 mg, the first generic version of Bristol-Myers Squibb's Sustiva®. The product is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 infection in adults and in pediatric patients at least 3 months old and weighing at least 3.5 kg.

Mylan is the world's largest producer of HIV/AIDS drugs, and more than 40% of the world's 20 million people being treated worldwide for HIV/AIDS depend on a Mylan antiretroviral product. In the U.S., there are an estimated 1.1 million people living with HIV.

"With the launch of Efavirenz, Mylan marks an important achievement in bringing more affordable treatment options to the HIV patient community," said Mylan CEO Heather Bresch. "Our global commitment to improving access to antiretroviral medicines for this important patient population spans more than a decade, and the U.S. launch bolsters our leadership in producing high-quality ARVs and positions us to continue to lead this important category in the future."

According to the FDA approval letter, Mylan was one of the first applicants to submit a substantially complete ANDA for Efavirenz Tablets USP, 600 mg, containing a Paragraph IV certification, and is eligible for 180 days of generic drug exclusivity. Efavirenz Tablets USP, 600 mg, had U.S. sales of approximately \$113 million for the 12 months ending Dec. 31, 2017, according to IQVIA.

Currently, Mylan has 208 ANDAs pending FDA approval representing approximately \$93.2 billion in annual brand sales, according to IQVIA. Forty-six of these pending ANDAs are potential first-to-file opportunities, representing \$42.1 billion in annual brand sales, for the 12 months ending July 31, 2017, according to IQVIA.

Mylan's Commitment to Stemming the Tide of HIV/AIDS

For more than a decade, Mylan has been a leader in providing access to quality, dependable and affordable ARVs in more than 100 countries around the world. This includes introducing in 2009 the first generic one-tablet-once-a-day combination for developing countries - only three years after the originator product launched in the U.S. Since that time, Mylan has been the first to market with nearly half of the new products approved under the FDA's U.S. President's Emergency Plan for AIDS Relief (PEPFAR) program. Mylan was also the first generic drug maker to develop a heat-stable version of a drug critical for second-line regimens, and is the leading supplier of pediatric ARVs, including taste-masked and dispersible formulations. Mylan has also long been a supporter of the patient community through the sponsorship of free community HIV/AIDS testing and clinical research. Learn more about Mylan's work with infectious disease [here](#). Watch [this video](#) to learn more about Mylan's commitment to people living with HIV/AIDS.

This press release includes statements that constitute "forward-looking statements," including with regard to Mylan expanding access to HIV/AIDS medicines; Mylan continuing to be at the forefront of working to meet the needs of this important patient community; and Mylan being eligible for 180 days of generic drug exclusivity. 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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