Mylan Introduces Symfi™ Triple Combo Once-Daily HIV Treatment in the U.S.

March 28, 2018

- Approval complements growing portfolio of cost-saving antiretroviral medications available to patients in the U.S., including recently announced Symfi Lo™ and Cimduo™

- All ARV regimens are being offered at a significant discount to the price of competing products to bring cost savings to the $20 billion U.S. ARV market

HERTFORDSHIRE, England and PITTSBURGH, March 28, 2018 /PRNewswire/ -- Global pharmaceutical company Mylan N.V. (NASDAQ: MYL) today announced that it will introduce in the U.S. a third cost-saving HIV combination. The U.S. Food and Drug Administration (FDA) approved Symfi™ (efavirenz, lamivudine and tenofovir disoproxil fumarate) 600 mg/300 mg/300 mg tablets, a once-daily, single-tablet regimen (STR), indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 40 kg.

"As the largest supplier of antiretrovirals by volume in the world, Mylan has a longstanding commitment to expanding affordable access to treatments for people living with HIV," said Mylan CEO Heather Bresch. "As we continue to grow our U.S. portfolio of ARV products, now including Symfi Lo™, Symfi™, and Cimduo™, we are providing access to patients and empowering them to choose the lower-cost ARV treatment option that is right fo them."

The introduction of Symfi™ comes after the FDA's recent approval of two Mylan ARVs: Cimduo™ (lamivudine and tenofovir disoproxil fumarate) 300 mg/300 mg tablets, a once-daily combination of two nucleo(t)side reverse transcriptase inhibitors, which is indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients weighing at least 35 kg.; and Symfi Lo™ (efavirenz, lamivudine and tenofovir disoproxil fumarate) 400 mg/300 mg/300 mg tablets, also approved for patients with HIV-1 in adults and pediatric patients weighing at least 35 kg.

Following FDA approval, Mylan launched Symfi Lo™ earlier in March. It expects Cimduo™ and Symfi™ to launch in the second quarter of 201

Symfi™ and Symfi Lo™ feature the same triple combination of molecules; however, Symfi Lo™ features a reduced dose of efavirenz while Symfi uses a dosing similar to other efavirenz products already on the market. The combination represented by Symfi™ (efavirenz, lamivudine and tenofovir disoproxil fumarate) 600 mg/300 mg/300 mg tablets is the most widely-taken ARV regimen outside of the U.S., with more than 7 million users worldwide in 2016[1].

In 2017, HIV was the category with highest pharmacy spend for Medicaid, the third highest for health exchange plans and the fifth highest for commercial plans.[2] According to IQVIA, total spending on HIV drugs has more than tripled since 2007, outpacing the approximate 60% growth in overall drug spending.

To help reduce the high cost of HIV treatment in the U.S, the list price of these Mylan ARVs will be discounted significantly from the wholesale acquisition cost of similar medicines on the market.

"Mylan has been on the forefront of bringing innovative delivery and dosage forms of ARVs to millions of patients in the developing world," said Mylan President Rajiv Malik. "We've already extended our reach to people in the U.S. living with HIV with the introduction of Symfi Lo™ and Cimduo™. Adding Symfi™ to our portfolio further strengthens our commitment to investing in developing and manufacturing these important products."

Lactic acidosis and hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues including lamivudine and tenofovir disoproxil fumarate. Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with hepatitis B virus and HIV who have discontinued lamivudine and tenofovir disoproxil fumarate.

Mylan's Commitment to the HIV/AIDS Patient Community

Mylan is the world's largest supplier by volume of HIV/AIDS therapies. More than 40% of the 20 million patients on treatment worldwide depend on a Mylan product every day. For more than a decade, Mylan has been a leader in providing access to quality, dependable and affordable ARVs in 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 tentatively approved by the FDA under PEPFAR. Mylan was also the first generic drug maker to develop for low- and middle-income countries a heat-stable version of a drug critical for second-line regimens, and is the leading worldwide supplier of pediatric ARVs, including taste-masked and dispersible formulations. Mylan has 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: all ARV regimens being offered at a significant discount to the price of competing products to bring cost savings to the $20 billion U.S. ARV market; that Mylan expects Cimduo™ and Symfi™ to launch in the second quarter of 2018; and that to help reduce the high cost of HIV treatment in the U.S, the list price of these Mylan ARVs will be discounted significantly from the wholesale acquisition cost of similar medicines on the 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: 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.

[1]https://clintonhealthaccess.org/content/uploads/2017/09/2017-ARV-Market-Report_Final-2.pdf
[2]http://lab.express-scripts.com/lab/drug-trend-report/2017-dtr

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Christine Waller (Media), 724.514.1968; Melissa Trombetta (Investors), 724.514.1813