Mylan Receives Tentative Approval for Combination HIV Treatment DTG/FTC/TAF Under FDA's PEPFAR Program

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- DTG/FTC/TAF is comprised of Dolutegravir, Emtricitabine, and Tenofovir Alafenamide Tablets, 50 mg/200 mg/25 mg -

- Mylan's DTG/FTC/TAF will be the first TAF-based fixed-dose combination to be offered to patients in developing countries being treated for HIV -

HERTFORDSHIRE, England and PITTSBURGH, Feb. 20, 2018 /PRNewswire/ -- Global pharmaceutical company Mylan N.V. (NASDAQ: MYL) today announced receipt of tentative approval from the U.S. Food and Drug Administration (FDA) under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) for its New Drug Application for Dolutegravir, Emtricitabine, and Tenofovir Alafenamide Tablets, 50 mg/200 mg/25 mg. The antiretroviral (ARV) will be immediately available in developing countries as a first-line regimen for people being treated for HIV/AIDS.

Mylan is the world's largest producer of HIV/AIDS drugs, and more than 40% of people being treated worldwide for HIV/AIDS depend on a Mylan antiretroviral product.

"The FDA's tentative approval of Mylan's Dolutegravir, Emtricitabine, and Tenofovir Alafenamide Tablets sets a new standard for affordable access for patients in countries hardest hit by HIV, as it's the first time a product combines dolutegravir and tenofovir alafenamide," said Mylan CEO Heather Bresch. "With limited funding, the world needs cost competitive and clinically effective products like this one, and Mylan is proud to work with partners to make it available and help reach the more than 15 million people living with HIV worldwide who still need access to treatment."

Mylan's ARV is a once-daily, fixed-dose combination of Dolutegravir, Emtricitabine and Tenofovir Alafenamide, the individual components that make up ViiV Healthcare's Tivicay® and Gilead's Descovy®. Mylan manufactures these products under licenses from the Medicines Patent Pool and Gilead Sciences, respectively. This is the first tentative approval of Tenofovir Alafenamide and comes just two years after the FDA approval of Descovy®. The combination of these agents is currently included as a "Recommended Initial Regimen for Most People with HIV" in the HIV guidelines of the U.S. Department of Health and Human Services.

"In the past decade, Mylan has committed itself again and again to bringing new therapeutic options to people living with HIV as quickly as possible and to as many people as possible," said Mylan President Rajiv Malik. "We are proud that nearly half of the FDA's tentative approvals under PEPFAR are Mylan products. In the last year alone, we have been the first company to receive approval for three new fixed-dose combination products that use a lower dose of Efavirenz, Dolutegravir, and now Dolutegravir in combination with Tenofovir Alafenamide."

The tablet will be the smallest sized single-tablet regimen available for patients in the developing world. It will be offered in a 90-day package as well as a 30-day one, potentially allowing patients fewer trips to the clinics for a refill.

Mylan's Commitment to the Treatment 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 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.

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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