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Mylan Receives Tentative Approval for "TLD" Under PEPFAR

Mylan's TLD is the first fixed-dose combination of its kind to be offered to patients being treated for HIV/AIDS
TLD is comprised of Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets, 50 mg/300 mg/300 mg

HERTFORDSHIRE, England and PITTSBURGH, Aug. 7, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL), a leading global pharmaceutical company, today announced receipt of tentative approval from the U.S. Food and Drug Administration under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) for its New Drug Application for Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate Tablets, 50 mg/300 mg/300 mg (TDF-3TC-DTG or "TLD"). TLD, an antiretroviral (ARV) fixed-dose combination, will be available in developing countries as a first-line regimen for people being treated for HIV/AIDS. Mylan's TLD combines molecules from three originator medicines - ViiV Healthcare's Tivicay® (via a license through the Medicines Patent Pool) and Epivir® and Gilead Science's Viread®.

Mylan President Rajiv Malik commented, "Our innovative TLD is a new medicine that will be available specifically to patients in the developing world being treated for HIV/AIDS. We know the challenges they face accessing high quality, affordable ARVs. That's why our scientists worked diligently to develop a medicine that combines three of the leading first-line regimens into a new, smaller tablet that patients have to take only once each day."

In July 2017, the WHO recommended national programs evaluate using DTG as a first-line therapy. The recommendation is based on the medicine's improved tolerability, higher antiretroviral efficacy, lower rates of treatment discontinuation, a higher genetic barrier to resistance and fewer drug interactions than other ARV drugs. Additionally, both the U.S. Department of Health and Human Services and the European AIDS Clinical Society include DTG as a preferred medicine on their HIV/AIDS treatment guidelines.

Globally, Mylan supplies life-saving ARVs to nearly 50% of patients being treated for HIV/AIDS in more than 100 developing countries. The company's comprehensive ARV portfolio includes 14 APIs and 50 finished dosage forms in first-line, second-line and pediatric formulations.

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 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.

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