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Mylan Signs Agreement with Gilead to Accelerate Access to Generic Single and Fixed-Dose Combination ARVs Containing Emtricitabine

Follows recent agreement with ViiV Healthcare in collaboration with Clinton Health Access Initiative to expand reach of pediatric formulation of Abacavir/Lamivudine to resource-limited settings

PITTSBURGH and HYDERABAD, India, Aug. 2, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced the establishment of a new agreement between its subsidiary Mylan Laboratories Limited and Gilead Sciences Inc. Under this agreement, Mylan has licensed the rights to produce and market generic versions of Gilead HIV/AIDS therapies containing Emtricitabine, including single and fixed-dose combinations. Emtricitabine is marketed by Gilead under the brand name Emtriva[®], and a fixed-dose combination of emtricitabine and tenofovir disoproxil fumarate is available under the brand name Truvada[®]. Emtricitabine also is a component of the "Quad," an investigational medicine that combines four Gilead medicines in a once-daily, single tablet regimen for the treatment of HIV-1 infection.

Mylan CEO Heather Bresch commented: "Access to affordable medicine continues to be an acute need in tackling HIV/AIDS, and once again we are delighted to be collaborating with Gilead in these efforts. Mylan is focused on expanding access to high-quality treatments to those in need around the world. Partnerships like this one ensure that patients in developing markets have access to important, recommended treatment options, like those containing emtricitabine."

Under previously-signed licensing agreements with Gilead, Mylan Laboratories obtained licensing rights to several Gilead products, which are currently in late-stage clinical development, including Elvitegravir, an investigational integrase inhibitor; Cobicistat, an investigational boosting agent to increase blood levels and allow once-daily dosing for certain HIV medicines; and the "Quad." Additionally, Mylan Laboratories obtained non-exclusive rights to produce and market active pharmaceutical ingredients and finished products, including generic versions of Viread[®] (Tenofovir Disoproxil Fumarate or TDF), Truvada[®] (Emtricitabine/Tenofovir Disoproxil Fumarate) and other TDF-based combinations in over 100 developing countries including India.

This agreement with Gilead follows a recent announcement by ViiV Healthcare of a novel public-private partnership with Mylan and the Clinton Health Access Initiative (CHAI) to expand access in resource-limited settings to a pediatric formulation of Abacavir/Lamivudine. ViiV Healthcare will oversee and fund the clinical development of this new, dispersible formulation and then license the necessary technology and resources to Mylan to facilitate regulatory submission. If approved, Mylan will produce and distribute the formulation in 115 resource-limited countries, including all low income, least developed countries and sub-Saharan Africa. Infants who are too young to swallow tablets need ARVs that are more child-friendly. This new dispersible formulation of Abacavir/Lamivudine will taste of strawberries, and will be developed and submitted for approval for children as young as twelve weeks old as part of their overall treatment regime.

Mylan's wide range of ARV products includes active pharmaceutical ingredients and 43 first- and second-line finished doses, nine of which are pediatric products. Approximately one-third of HIV/AIDS patients in developing countries depend on a Mylan ARV product.

Mylan is a global pharmaceutical company committed to setting new standards in health care. 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 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 1,100 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately one-third of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in approximately 150 countries and territories. Our workforce of more than 18,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. But don't take our word for it. See for yourself. See inside. mylan.com

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