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Mylan receives tentative FDA approval for pediatric formulations of abacavir/lamivudine through innovative collaboration with ViiV Healthcare and Clinton Health Access Initiative

PITTSBURGH and LONDON, Dec. 4, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Laboratories Limited has received tentative approval from the U.S. Food and Drug Administration (FDA) for its New Drug Applications (NDAs) for two dosages of abacavir/lamivudine tablets for oral suspension for the treatment of HIV-1 infection in pediatric patients. This is the first version of abacavir/lamivudine with scoring to allow for dose adjustment and is also flavored. The FDA's tentative approval through the President's Emergency Plan for AIDS Relief (PEPFAR) program means the formulations meet all of the agency's quality, safety and efficacy standards.

The tentative approval follows a 2012 agreement between Mylan, Clinton Health Access Initiative (CHAI) and ViiV Healthcare to transfer the necessary technology and resources to facilitate regulatory authority submission, production and distribution of the new formulation, at low cost, to a total of 115 resource limited countries including all low-middle income, least developed countries and sub-Saharan Africa. Mylan's products are expected to be eligible for purchase in early 2015.

The fixed dose combination of abacavir and lamivudine tablets for oral suspension 60 mg/30 mg and 120 mg/60 mg is indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents for pediatric patients.

More than 70% of the approximately 3.4 million children living with HIV worldwide do not have access to appropriate care and medicines[1]. Improving those numbers will require medicines that are palatable to children and affordable to those living in resource-limited settings.

"The approval of abacavir and lamivudine tablets for oral suspension for marketing in developing markets demonstrates our commitment to providing the world's 7 billion people with access to medicine and our continued leadership in enhancing access to ARVs to patients in developing countries," Mylan CEO Heather Bresch said. "This new flavored, pediatric formulation is designed to help parents and caregivers give accurate doses of the medication depending on the weight of the child. The innovative work being done at Mylan, in combination with our partnership with ViiV and CHAI, has enabled us to develop this new product to treat children with HIV, a particularly vulnerable population."

Dr. Dominique Limet, CEO ViiV Healthcare commented on the news, "Based on the need clearly identified by the Clinton Health Access Initiative in 2012, ViiV Healthcare became the first pharmaceutical company to fully fund the entire development process for a pediatric formulation of an HIV medicine which would then be transferred to another company for manufacture and distribution in the developing world. I congratulate Mylan on this approval, made even more meaningful for us at ViiV Healthcare as it proved that this innovative approach to partnership can work."

David Ripin, Executive Vice President and Chief Scientific Officer for CHAI said "We are pleased that our partnership with ViiV and Mylan has resulted in an important new pediatric formulation, moving from concept to FDA tentative approval in less than two years. The new, flavored dispersible medication will help meet the needs of over 500,000 children being treated for HIV in low middle income countries and demonstrates leadership and innovation on the part of both originators and generic suppliers together to address the needs of pediatric patients worldwide. We are pleased to have participated in this innovative public-private partnership with the support of the UK Department for International Development."

About abacavir/lamivudine
Abacavir/lamivudine is a fixed-dose combination containing two nucleoside reverse transcriptase inhibitors (NRTIs). NRTIs interfere with the action of the reverse transcriptase enzyme to prevent the virus from replicating.

Abacavir/lamivudine was approved in the US in August 2004 under the brand name Epzicom and in Europe in December 2004 under the brand name Kivexa.

Kivexa and Epzicom are registered trademarks of the ViiV Healthcare group of companies.

About President's Emergency Plan for AIDS Relief (PEPFAR)
PEPFAR is the U.S. Government initiative to help save the lives of those suffering from HIV/AIDS around the world. This historic commitment is the largest by any nation to combat a single disease internationally. In May 2004, in support of the President's Emergency Plan, FDA announced a new initiative to help ensure that those being served by the Presidents' Plan would receive

safe, effective, and quality manufactured antiretroviral drugs. This new initiative included an expedited review process. Through guidance and an active outreach program to the pharmaceutical industry, FDA actively encouraged any sponsors worldwide to submit U.S. marketing applications for single entity, fixed dose combination (FDC), and co-packaged versions of previously approved antiretroviral therapies - even if there was still patent or exclusivity market protection for the product in the U.S.

Important Safety Information (ISI) for abacavir and lamivudine tablets 60 mg/30 mg and 120 mg/60 mg for oral suspension
Please consult the full Prescribing Information for labeled safety information for abacavir and lamivudine tablets for oral suspension.

BOXED WARNING: RISK OF HYPERSENSITIVITY REACTIONS, LACTIC ACIDOSIS AND SEVERE HEPATOMEGALY, AND EXACERBATIONS OF HEPATITIS. See full Prescribing Information for complete boxed warning.

- Serious and sometimes fatal hypersensitivity reactions have been associated with abacavir-containing products.
- Hypersensitivity to abacavir is a multi-organ clinical syndrome.
- Patients who carry the HLA-B*5701 allele are at high risk for experiencing a hypersensitivity reaction to abacavir.
- Discontinue abacavir and lamivudine as soon as a hypersensitivity reaction is suspected. Regardless of HLA-B*5701 status, permanently discontinue abacavir and lamivudine if hypersensitivity cannot be ruled out, even when other diagnoses are possible.
- Following a hypersensitivity reaction to abacavir, NEVER restart abacavir and lamivudine or any other abacavir-containing product.
- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues.
- Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV) -1 and have discontinued lamivudine. Monitor hepatic function closely in these patients and, if appropriate, initiate anti-hepatitis B treatment.

CONTRAINDICATIONS

- Presence of HLA-B*5701 allele
- Previous hypersensitivity reaction to abacavir or any other component of the product.
- Hepatic impairment.

WARNINGS AND PRECAUTIONS

- Hepatic decompensation, some fatal, has occurred in HIV-1/Hepatitis C Virus (HCV) co-infected patients receiving combination antiretroviral therapy and interferon alfa with or without ribavirin. Discontinue abacavir and lamivudine as medically appropriate and consider dose reduction or discontinuation of interferon alfa, ribavirin, or both.
- Immune reconstitution syndrome and redistribution/accumulation of body fat have been reported in patients treated with combination antiretroviral therapy.
- Administration of abacavir and lamivudine is not recommended in patients receiving other products containing lamivudine- or zidovudine-containing products or emtricitabine-containing products.
- Pancreatitis: Use with caution in pediatric patients with a history of pancreatitis or other significant risk factors for pancreatitis. Discontinue treatment as clinically appropriate.
- Abacavir and lamivudine tablets 60 mg/30 mg and 120 mg/60 mg for oral suspension contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with phenylketonuria.

ADVERSE REACTIONS

- Abacavir and lamivudine: The most commonly reported adverse reactions of at least moderate intensity (incidence > 5%) in an adult HIV-1 clinical trial were drug hypersensitivity, insomnia, depression/depressed mood, headache/migraine, fatigue/malaise, dizziness/vertigo, nausea and diarrhea.
- Abacavir: The most commonly reported adverse reactions of at least moderate intensity (incidence > 5%) in pediatric HIV-1 clinical trials were fever and/or chills, nausea and vomiting, skin rashes and ear/nose throat infections.
- Lamivudine: The most commonly reported adverse reactions of at least moderate intensity (incidence > 15%) in pediatric patients were fever and cough.

DRUG INTERACTIONS

- Ethanol: Decreases elimination of abacavir
- Methadone: An increased methadone dose may be required in a small number of patients

USE IN SPECIFIC POPULATIONS

- Pregnancy: Category C abacavir and lamivudine should be used during pregnancy only if the potential benefit justifies the potential risk.
- Nursing mothers: Both for the potential for HIV-1 transmission and potential for serious adverse reactions in nursing infants, should be instructed not to breastfeed if they are receiving abacavir and lamivudine
- Abacavir and lamivudine is not recommended in patients with creatinine clearance less than 50 mL per min.
- Abacavir and lamivudine are contraindicated for patients with hepatic impairment.

About Clinton Health Access Initiative
CHAI was founded in 2002 with a transformational goal: help save the lives of millions of people living with HIV/AIDS in the developing world by dramatically scaling up antiretroviral treatment. Learn more about CHAI here: www.clintonhealthaccess.org

About Mylan Laboratories
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 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 1,300 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately 40% 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 140 countries and territories. Our workforce of more than 20,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. Learn more at mylan.com.

About ViiV Healthcare
ViiV Healthcare is a global specialist HIV company established in November 2009 by GlaxoSmithKline (LSE: GSK) and Pfizer (NYSE: PFE) dedicated to delivering advances in treatment and care for people living with HIV. Shionogi joined as a shareholder in October 2012. The company's aim is to take a deeper and broader interest in HIV/AIDS than any company has done before and take a new approach to deliver effective and new HIV medicines, as well as support communities affected by HIV. For more information on the company, its management, portfolio, pipeline, and commitment, please visit www.viivhealthcare.com.

References:
1. WHO, UNAIDS and UNICEF, Global HIV/AIDS response: epidemic update and health sector progress towards universal access: progress report 2011, Geneva, 2011.

Mylan cautionary statement regarding forward-looking statements: This press release includes statements that constitute "forward-looking statements," including with regard to Mylan's product approvals, sales of products and strategy, future growth and performance. 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: risks inherent in legal and regulatory processes; the impacts of competition; changes in economic and financial conditions of Mylan's business; strategies by competitors or other third parties to delay or prevent product introductions; 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.

GlaxoSmithKline cautionary statement regarding forward-looking statements: GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under Item 3.D "Risk factors" in the company's Annual Report on Form 20-F for 2013.