Mylan Receives WHO Approval for Innovative 'Second-Line-in-a-Box' HIV/AIDS Treatment

- Company also receives WHO approval for two additional ARVs -
- Products help to increase access to more affordable, more convenient medicines for patients in developing countries -

PITTSBURGH, Dec. 20, 2011 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Laboratories Limited (formerly Matrix Laboratories Limited) has received approval for three antiretroviral (ARV) therapies used to treat HIV/AIDS under the World Health Organization's (WHO) Prequalification of Medicines Programme. The products include:

- Atazanavir Capsule, 300 mg, Ritonavir Tablet, 100 mg (heat-stable), and Tenofovir Disoproxil Fumarate and Lamivudine Tablet 300 mg/300 mg, or "second-line-in-a-box"
- Fixed-dose combination Atazanavir Sulfate and Ritonavir Tablets, 300 mg/100 mg
- Fixed-dose combination Abacavir Sulfate, Lamivudine and Zidovudine Tablets, 300 mg/150 mg/300 mg

Mylan President Heather Bresch said: "With these three approvals, Mylan will further enhance our portfolio of more convenient, more affordable treatment options for people in the developing world living with HIV/AIDS. In particular, we are proud to deliver on a previous commitment that we made through an announcement with President Bill Clinton on August 6, 2009[1], to lower the price of second-line treatments for patients with drug-resistant HIV in developing countries. Further, these product combinations and packaging solutions are an example of our continued commitment to innovation in an effort to increase treatment adherence and effectiveness. By bringing these medicines to market through WHO's Prequalified Medicines Programme, we are again delivering on our promise to expand access to critical, life-saving ARV medicines for patients who need them in the developing world."

Atazanavir Capsule, 300 mg, Ritonavir Tablet, 100 mg (heat-stable), and Tenofovir Disoproxil Fumarate and Lamivudine Tablet 300 mg/300 mg, is a co-packaged product that makes available a once-daily treatment for patients who have developed resistance to standard first-line ARVs. The product can also be used as a first-line treatment and makes available four drugs in only three forms, with Tenofovir and Lamivudine combined into a single tablet. Mylan will sell the products in one co-package - a "second-line-in-a-box," which was designed to reduce the pill burden for patients and can help to increase treatment adherence through a more convenient packaging presentation. In addition, when compared to other drugs in the protease inhibitor class, Atazanavir is less likely to cause dyslipidemia, a condition associated with elevated lipid levels in the body. Atazanavir, Ritonavir, Tenofovir Disoproxil Fumarate and Lamivudine are the generic versions of Bristol-Myers Squibb's Reyataz®, Abbott Laboratories' Norvir®, Gilead Sciences' Viread® and GlaxoSmithKline's Epivir®, respectively. This product was developed in line with WHO's "Expression of Interest" application process[2] - an initiative intended to increase access to and the affordability of HIV/AIDS treatments in partnership with United Nations programs.

Atazanavir Sulfate and Ritonavir Tablets, 300 mg/100 mg, are the first heat-stable, fixed-dose combination of Atazanavir Sulfate and Ritonavir. This product offers a convenient once-a-day dosing regimen. It also provides a cost-effective second-line treatment option for people living with HIV/AIDS.[3] Atazanavir and Ritonavir are the generic versions of Bristol-Myers Squibb's Reyataz and Abbott Laboratories' Norvir, respectively.

Abacavir Sulfate, Lamivudine and Zidovudine Tablets, 300 mg/150 mg/300 mg, offer a fixed-dose combination tablet that is used as a second-line treatment of HIV/AIDS for patients with a limited tolerance for other treatment combinations. The drugs are available in one tablet that must be taken twice daily, instead of three separate tablets. The reduced pill burden may help to increase treatment compliance for patients with HIV/AIDS. This fixed-dose combination product is the generic version of GlaxoSmithKine's Trizivir®.

A WHO Prequalification indicates that a drug meets international safety, efficacy and manufacturing quality standards. With such approval, Matrix can sell the treatment in most countries outside the U.S. and Europe.

Mylan's wide range of ARV products includes active pharmaceutical ingredients and 39 first- and second-line finished doses, eight of which are pediatric products. The company's emphasis on producing affordable products has allowed it to drive down the average annual cost per patient of effective therapies. Approximately one-third of HIV/AIDS patients in developing countries depend on a Mylan ARV product.

Mylan Inc. ranks among the leading generic and specialty pharmaceutical companies in the world and provides products to customers in more than 150 countries and territories. The company maintains one of the industry's broadest and highest quality product portfolios supported by a robust product pipeline; operates one of the world's largest active pharmaceutical ingredient manufacturers; and runs a specialty business focused on respiratory, allergy and psychiatric therapies. For more information about Mylan, please visit www.mylan.com. For more information about generic drugs, please visit www.ChoosingGenerics.com.

[1] Please refer to Mylan's August 6, 2009 announcement to learn more.

[2] Mylan's "second-line-in-a-box" treatment was developed in line with WHO's 10th invitation to participate in the "Expression of Interest" product application process.

[3] Mylan recently received tentative approval for this product from the U.S. Food and Drug Administration through the Presidents Emergency Plan for AIDS Relief. Learn more.

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