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Global Access and Partnerships Program

As December 2011 comes to a close, Janssen would like to provide an end-of-the-year update.

This year has been busy for our Global Access and Partnerships Program. This newsletter will provide you with an update on our discussions with the Medicines Patent Pool, the expansion of our *rilpivirine* licenses and our efforts to extend access to treatment for people living with HIV in the United States.

Medicines Patent Pool Decision

Earlier this year, Janssen **responded** to a formal invitation from the Medicines Patent Pool (MPP) to begin negotiations to license patents for our HIV medicines. We expressed confidence that our current agreements with generic manufacturers provided the best route to expand access to patients in need of our HIV drugs. After meeting with the MPP in the spring, we agreed to revisit our decision. So it is after a period of thorough deliberation and discussion, we have decided not to enter into negotiations with the MPP today.

Providing effective and sustainable access to medicines is an important pillar of our commitment to healthcare around the world. At the heart of our Global Access & Partnership Program is our responsibility and commitment to the patients in need of our HIV medicines in resource-limited countries.

As you know, our current HIV portfolio is comprised of three drugs: PREZISTA® (*darunavir*) and INTELENCE® (*etravirine*), which are approved for use in treatment-experienced patients (3rd-line) in resource-limited countries, and EDURANT® (*rilpivirine*) for treatment-naïve patients, which received approval in the United States and Europe earlier this year but is not yet approved for use in resource-limited countries.

Our HIV medicines are not yet included in World Health Organization (WHO) treatment guidelines for 1st- or 2nd-line treatment. Nor are they part of WHO Treatment Optimization short-term objectives over the next 1-3 years. Of the three, only *darunavir* is currently being considered in the medium-term (4 – 6 years) as a possible candidate for 2nd-line treatment for adult and pediatric patients. Because WHO treatment guidelines drive the public health treatment focus and national guidelines in resource-limited countries, the current clinical demand for our medicines is extremely limited there.

In addition, HIV resistance testing is not widely available in resource-limited settings, which makes the contruction of active treatment regimens challenging. As a result treatment of 3rd-line patients is largely restricted to centers of excellence where physicians have specialist knowledge

and/or access to resistance testing.

For *rilpivirine*, its current approval in the U.S. and Europe is for patients with a viral load of less than 100,000 copies/mL. Assuming a similar indication in resource limited countries, this also will require special management to assure *rilpivirine* is appropriately used where viral load testing is not available.

As *darunavir* and *etravirine* are often a patient's last treatment options in resource-limited settings their appropriate use is critical. Therefore one of the important components of our access efforts is medical education. In resource-limited countries, we focus on effective and appropriate use of our HIV medicines, as well as specialized workshops on HIV resistance and the management of patients with HIV drug resistance. In the last 12 months, more than 150 physicians have attended these resistance workshops, cohosted with the St. Stephens AIDS Trust, in Botswana, Ghana, Kenya, Namibia, Nigeria, South Africa, Uganda, and Zambia. The workshops focus on "trainer of trainers" (TOT) and share medical knowledge with leading HIV clinicians and educators, so that they can train other clinicians on appropriate HIV regimens for 3rd-line patients.

We will continue to work to expand sustainable and affordable access to our HIV compounds, both as single agents and fixed-dose combinations through our 9 existing direct agreements with generic manufacturers, and future new licensing agreements. We are also continuing to broaden the geographic reach of our agreements as we build our operational capacity to support the delivery of our HIV medicines.

Our commitment to appropriate treatment for patients in resource-limited countries and the limited clinical demand based on their approved indication are two of the reasons why today, we continued to be confident that our existing access efforts and licensing agreements with generic manufacturers provide the best route to expand access to patients in need of our HIV medicines in today and in the near-term.

Rilpivirine Generic Licenses Expanded

In January, we announced that we had granted multiple non-exclusive licenses to generic manufacturers to manufacture, market and distribute *rilpivirine* in resource-limited countries. We are now pleased to announce we have completed addendums to these existing **agreements** with Aspen Pharmacare, Emcure Pharmaceuticals Ltd, Hetero Drugs Ltd, and Strides Acrolab.

These addendums will provide additional rights to develop another FDC – that of 25 mg *rilpivirine*, 300 mg *tenofovir disoproxil fumarate* and 200 mg *emtricitabine*, to manufacture compound API, and to expand the territory from 66 to 112 countries, in which the companies can commercialize the 25 mg generic version of *rilpivirine*, pending approval, as a single agent and as two FDC products. These countries are home to 82% of patients living with HIV worldwide. The execution of these agreements is an important step in enabling generic manufacturing capabilities, and expanding the scope of our access program for patients in need of our HIV medicines.

> Addendums include rights to develop another FDC, manufacture compound API, and expands the territory from 66 to 112 countries for generic *rilpivirine*, pending approval, as a single agent and as two FDC products.

HIV Medicine Discounts to Address Patient Waiting Lists in the United States

In our conversations about global access to medicines, we sometimes overlook the important work being done to address the needs of patients in the United States. In the U.S. today, HIV disproportionately affects the

impoverished and disenfranchised. Additionally, AIDS Drug Assistance Programs (ADAPs) – a network of federal and state funded programs that provide life-saving HIV treatments to low income, uninsured, and underinsured individuals living with HIV/AIDS – are currently facing a funding crisis, resulting in many HIV patients being put on waiting lists to receive their HIV medicines.

This month, my colleagues at Janssen Therapeutics announced an enhanced agreement with the ADAP Crisis Task Force (ACTF), to provide additional discounts and rebates to ADAPs on all of its HIV medications to help address the needs of patients impacted by the ADAPs funding crisis. These discounts are in addition to the supplemental discounts already mandated by law, and the additional discounts we agreed to provide in 2010 at the request of the ADAP Crisis Task Force. Janssen agreed to the additional discounts because of our concern about the impact of ADAP funding crisis is having on patient's abilities to access their medicines. We believe these additional discounts will help remove barriers to access by helping to eliminate ADAP waiting lists and allowing ADAPs to maintain their current formularies. ADAPs, a network of federal and state funded programs that provide life-saving HIV treatments to low income, uninsured, and underinsured individuals living with HIV/AIDS nationwide.

Our comprehensive HIV access strategy in resource-limited settings continues to evolve and expand and we look forward to sharing exciting new milestones and activities with you in 2012. As always, please don't to hesitate to contact me if you have any questions and I wish you a very happy holiday season.

Sincerely,

Will Stephens
Vice President, Global Access and Partnerships
Janssen Global Services, LLC

**Actual approved users are determined by local health authorities. Please check local package insert for precise indication.*