Will Stephens
Vice President, Global Access & Partnerships

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15 December 2011

Robert Weismann and Peter Maybarduk
Public Citizen
1600 20th Street NW
Washington, D.C. 20009
(202) 588-1000

RE: Your letter of November 7th, 2011

Dear Mr. Weismann and Mr. Maybarduk,

Thank you for your letter concerning the intention of Johnson & Johnson to announce its decision to formally enter negotiations with the Medicines Patent Pool to license the company's patents and related data to the Pool.

We believe that voluntary licensing is an ideal mechanism by which to expand access and reduce prices to HIV drugs. To that end, during 2011 we have completed five new license agreements with generic manufacturers for our newest HIV medicine *rilpivirine*. The geographic scope of our access efforts now spans 112 low- and middle-income countries. In addition we have expanded a number of our existing voluntary licensing agreements as well as our agreement with Gilead for the development of a once-daily fixed dose combination of EDURANT® (rilpivirine) and Gilead's Truvada® (*emtricitabine 200 mg/tenofovir 300 mg*). We will continue to build on and enhance our generic licensing agreements.

As a company policy, we do not disclose or discuss the details of our licensing agreements. For your information, I've attached a recent update that we shared on our access efforts and agreements.

We support the MPP Foundation in their initiative to expand voluntary licensing and are arranging for a meeting with them during which we will share the outcome of our evaluation process. After we have met with them, we will certainly make ourselves available to meet with your team to provide any further clarification and answer your questions.

With best regards,

Will Stephens
VP Global Access and Partnerships Program, Janssen global Services Inc

Sent on behalf of William C. Weldon

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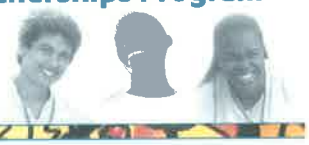
Global Access and Partnerships Program

The Janssen Global Access & Partnerships Program (GAPP) team is delighted to share some of the exciting results of our recent efforts to ensure that HIV patients worldwide have sustainable and affordable access to our HIV medicines today!



Our licensing agreements with generic manufacturers in South Africa and India are key to providing access to our HIV drugs today. They play a critical role in making sure that our medicines are affordable. Importantly, they go beyond simply licensing our intellectual property. We require our generic partners to meet the essential operational requirements of effective HIV drug access, such as: securing timely in-country registrations; developing and/or improving supply chain; ensuring quality drug products; and monitoring the safety and effectiveness of our products. Medical education is also a cornerstone of our access program. In support of these efforts we collaborate with our generic partners to address product awareness and/or medical information needs. We continue to build on and enhance our generic licensing agreements, recent developments include:

- **PREZISTA® (*darunavir*):** In keeping with our commitment to affordability, we have reduced the Special Access Price of PREZISTA® to US$2.22/day ex-factory from Aspen Pharmacare for sub-Saharan Africa (SSA) and least developed countries (LDCs) — from US$3/day, a price reduction of 26 percent. The new price will be effective as of 17th October 2011.
  - In addition, our **original agreement** with Aspen Pharmacare for PREZISTA® now also incorporates additional formulations of PREZISTA® for SSA and LDCs — including 75mg and 150mg formulations for HIV treatment-experienced pediatric patients.*
- ***Rilpivirine* (TMC278):** We've added Strides Arcolab and Emcure Pharmaceuticals to our list of generic partners for *rilpivirine* — in addition to our three previous **agreements** with Aspen, Hetero Drugs, and Matrix Laboratories. In order to provide a head start for these manufacturers to develop generic versions of the single agent and FDC (with 300mg *tenofovir* and 300mg *lamivudine*), four of these agreements were signed before we received our first regulatory approval in the USA.
- **EDURANT® (TMC278):** We recently signed a new license agreement with Aspen for branded EDURANT® (a 25mg single agent) in SSA, where Aspen will be responsible for registration and distribution.
- **Medicines Patent Pool:** We continue to receive questions around potential licensing of our HIV medicines to the Medicines Patent Pool (MPP). In the coming weeks, we will come to a decision on whether to enter into formal negotiations with them.

Gilead Agreement for FDC of EDURANT® and Truvada®

In July, we expanded our **original agreement** with Gilead Sciences, Inc., to develop a once-daily FDC of EDURANT® and Gilead's Truvada® (*emtricitabine 200 mg/tenofovir 300 mg*). In August, the U.S. Food & Drug Administration approved the FDC under the brand name COMPLERA™ (*rilpivirine tenofovir emtricitabine*) for treatment-naïve patients. As you know, FDCs are particularly important in resource-poor countries as they help to simplify HIV treatment and are preferred by public health treatment programs.

Our agreement now defines each company's responsibilities for introducing the FDC into rest of the world (ROW) countries (beyond the original territories). The companies will split these responsibilities along regional lines. As such, the responsible party will either bring to market the branded FDC product or enable generic manufactures to manufacture and bring to market a generic version of the FDC product.

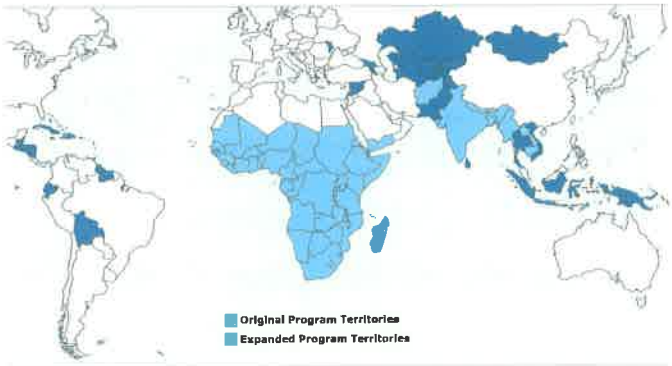
Registrations in Sub-Saharan Africa

We have made good progress with regulatory approvals for PREZISTA® 300mg and PREZISTA® 600mg in SSA; from our list of 21 priority countries, we have received PREZISTA® 300mg approval in 17 countries and PREZISTA® 600mg approval in six countries. Regulatory submissions and approvals for INTELENCE® (*etravirine*) 100mg are also making progress in the region, and it recently received approval in South Africa. Expedited registration process requests were submitted in July 2011 for 25mg EDURANT® as well as pediatric formulations of PREZISTA® (75mg and 150mg) in South Africa. As soon as expedited registration process is granted, we will proceed with the submission of the registration dossiers.

Broadening the Geographic Scope of Access

We are constantly striving to reach more of those in need of our HIV medicines in resource-limited countries. I am very pleased to announce that we are in the process of increasing our Program's geographic scope from 65 to 112 countries for EDURANT™ (*rilpivirine*); new countries have been added throughout Asia, Eastern Europe, and Latin America (*see map below*). These countries are home to 82% of people living with HIV worldwide.

Our Program now covers countries home to 82% of people living with HIV worldwide.



Treatment Optimization

Today first-line treatment remains the priority in many resource-limited countries. However PREZISTA® and INTELENCE® are currently indicated for treatment-experienced patients and so demand for these medicines is currently limited.

However, interest is growing in the potential application of *darunavir* as second-line treatment in the developing world. *Darunavir*, in combination with *ritonavir*, was recently mentioned in the World Health Organization Treatment Optimization recommendations as a possible candidate for second-line treatment for both adult and pediatric patients in resource-limited settings. We firmly believe that a global move towards simple, safe and optimal treatment regimens is in the best interest of patients and public health policy. Our company is a strong proponent of optimizing treatment and we are working to develop new/novel FDCs with our products and to simplify existing formulations to provide the best and safest options for patients worldwide.

We continue to build upon our comprehensive access strategy for our HIV medicines in resource-limited settings and look forward to sharing additional milestones in the months to come. As always, please don't to hesitate to contact me if you have any questions.

Sincerely,

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

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