PR Newswire

Janssen Announces Intent Not to Enforce Patents for Darunavir in Resource-Limited Settings

Press Release

November 29, 2012

Policy Aims to Support a Sustainable Supply of Medically Acceptable Generic Darunavir in Sub-Saharan Africa (SSA) and Least Developed Countries (LDCs)

RARITAN, N.J., Nov. 29, 2012 /PRNewswire/ -- The Janssen Pharmaceutical Companies of Johnson & Johnson today announced their intention not to enforce the patents they own and control on the antiretroviral (ARV) drug darunavir provided the darunavir product is medically acceptable and is used only in resource-limited settings.(1) This announcement is intended to assure generic manufacturers that they may manufacture high quality darunavir product used in SSA and the LDCs without a concern that Janssen will accuse these activities of infringing its darunavir patents.

This new policy anticipates a greater future need to supply affordable generic versions of darunavir (brand name PREZISTA()) for the treatment of people living with HIV in the territory, and is consistent with the Company's focus on access to medicines in those countries with the highest rates of HIV infection and economic vulnerability.

"We are pleased to take this significant step toward bringing our innovations to meaningfully impact the health of people living with HIV and enhance access to our medicines for those in need," said Paul Stoffels, Scientific Officer and Worldwide Chairman, Pharmaceuticals, Johnson & Johnson. "As part of this commitment, we believe that an effective access strategy includes responsible intellectual property management and that intellectual property should not be a barrier to ensuring a sustainable supply of medically acceptable darunavir in the world's poorest countries."

Darunavir administeredwith ritonavir and in combination with other antiretrovirals is currently indicated for highly treatment-experienced HIV patients (third-line) in SSA and has been recommended by the World Health Organization.(2) It is also included in several national HIV treatment guidelines in SSA for use with highly treatment-experienced patients. Janssen recognizes that, as more patients fail their initial treatment regimens due to HIV drug resistance in SSA and LDCs, demand and uptake of darunavir will only grow.

Under this policy Janssen will not enforce its darunavir patent rights, provided the generic versions of darunavir produced or supplied by generic manufacturers are quality, medically acceptable, and used

only in the defined territory. Manufacturers are still responsible for obtaining permissions from other darunavir patent holders and health authorities where appropriate.

Janssen will continue to ensure the availability and appropriate use of PREZISTA() in SSA and LDCs through its existing licensing agreement and partnerships.

About Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, the Pharmaceutical Companies of Johnson & Johnson, we are dedicated to addressing and solving some of the most important medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Janssen Research & Development, LLC is part of the Janssen Pharmaceuticals Companies of Johnson & Johnson. Please visit http://www.janssen.com/our-caring.html for more information.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of healthcare products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the healthcare industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments).

(1) Resource-limited settings under this policy include all Least Developed Countries ("LDCs") as defined by the United Nations (http://www.unohrlls.org/en/ldc/25/) and the countries of sub-Saharan Africa (SSA) which are not classified as LDCs.
(2) World Health Organization. Antiretroviral Therapy for HIV Infection in Adults and Adolescents:

Recommendations for a Public Health Approach, 2010 Revision.
http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf

SOURCE Janssen Pharmaceutical Companies of Johnson & Johnson

CONTACT: Seema Kumar, +908-405-1144; Daniel De Schryver, +32 14 60 3030

Web Site: http://www.janssen.com

See the topic on aegis.org