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Janssen Submits Marketing Authorisation Application to European Medicines Agency for a Fixed-Dose Combination Tablet of HIV-1 Medicine Darunavir with Cobicistat

Beerse, Belgium, Oct 15, 2013 - Janssen-Cilag International NV (Janssen), today announced it has submitted a Marketing Authorisation Application to the European Medicines Agency seeking approval for a once-daily single tablet fixed-dose antiretroviral combination product containing darunavir, a protease inhibitor developed by Janssen, with cobicistat, a pharmacokinetic enhancer or boosting agent, developed by Gilead Sciences, Inc. (Gilead) for use in combination with other human immunodeficiency virus (HIV-1) medicines.

Once-daily darunavir is marketed as PREZISTA® in the European Union. PREZISTA® is always taken with and at the same time as ritonavir, a boosting agent, with food and in combination with other HIV medicines. If approved, the fixed-dose combination tablet will be marketed under a new brand name and will, for the first time, offer an option that eliminates the need to take a boosting agent in a separate tablet with once-daily darunavir.

In June 2011, Janssen announced a license agreement with Gilead for the development and commercialization of a once-daily, single tablet fixed-dose combination product of darunavir and Gilead's cobicistat. Under the terms of the agreement, Janssen and its affiliates are responsible for the formulation, manufacturing, registration, distribution and commercialization of the darunavir and cobicistat fixed-dose combination worldwide. Gilead retains sole rights for the manufacture, development and commercialization of cobicistat as a stand-alone product and for use in combination with other agents.

"Over the last six years, Janssen has launched three therapies for people living with HIV and is committed to further evaluating HIV therapies for a broad range of patients. We are therefore excited to be applying for marketing authorization for a single tablet combination product which includes darunavir, the leading protease inhibitor worldwide, with an alternative boosting agent," said, Johan van Hoof, Therapeutic Area Head, Infectious Diseases and Vaccines, Janssen. "This filing demonstrates our ongoing commitment to develop new HIV treatment options and fixed-dose treatment regimens for those living with the disease. The ultimate goal is to help all patients achieve an undetectable viral load and a better quality of life."

About PREZISTA® (darunavir)
Darunavir, co administered with low dose ritonavir, is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult and paediatric patients from the age of 3 years and at least 15 kg body weight.

Since its initial approval in 2007, darunavir has also been indicated for use in HIV-1 infected treatment-naïve and treatment-experienced adult patients, including those who have been highly pre-treated, in combination with ritonavir and other ARTs. For treatment-experienced adult patients, the licensed dosing for darunavir (DVR) is 600 mg taken with 100 mg ritonavir twice daily with food or 800 mg taken with 100 mg ritonavir once daily with food for patients with no DRV Resistance Associated Mutations (RAMs)[1] and who have plasma HIV-1 RNA <100,000 copies/mL and CD4+ cell count ≥ 100 cells x 10^6/L. For treatment-naive adult patients, the licensed dosing for darunavir is 800 mg taken with 100 mg ritonavir once daily with food.

Important Safety Information

In the registrational studies, darunavir was generally well tolerated. The majority of the adverse reactions reported in patients who initiated therapy with darunavir co-administered with 100 mg ritonavir were mild to moderate in severity. The most frequent adverse reactions reported in clinical trials and as spontaneous reports are diarrhoea, nausea, rash, headache and vomiting. The most frequent serious reactions are acute renal failure, myocardial infarction, immune reconstitution syndrome, thrombocytopenia, osteonecrosis, diarrhoea, hepatitis and pyrexia. Please see the Summary of Product Characteristics for a complete list of all possible side effects.

Before taking darunavir, patients should tell their doctor if they have any medical conditions, including liver problems, including hepatitis B or C, diabetes, symptoms of infections, change in body fat, haemophilia, musculoskeletal problems, or allergy to sulfa medicines and should tell their doctor if they are pregnant or planning to become pregnant, or are nursing.

Darunavir should not be used in patients allergic (hypersensitive) to it or ritonavir or with severe liver problems.

Due to potential drug interactions, patients should talk to their healthcare provider about all the medicines they are taking or plan to take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Darunavir does not cure HIV infection or AIDS, and does not prevent passing HIV to others.

Please see full Summary of Product Characteristics for more details.

About Janssen
At Janssen, we are dedicated to addressing some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Janssen-Cilag International NV is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

More information about Janssen can be found at www.janssen-emea.com.

(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-Cilag International NV, 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 health care 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 health care 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 December 30, 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.)

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[1] V11I, V32I, L33F, I47V, I50V, I54L/M, T74P, L76V, I84V, L89V

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