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EUROPEAN COMMISSION APPROVES PREZISTA® (darunavir) 800 MG TABLET ONCE A DAY REDUCING THE NUMBER OF PILLS TAKEN BY PEOPLE LIVING WITH HIV

Cork, Ireland [16 January, 2013] – Janssen R&D Ireland announced today that the European Commission (EC) has approved a new PREZISTA® (darunavir) 800mg tablet allowing people living with HIV to take one darunavir tablet once a day. Darunavir is indicated in combination with other antiretrovirals for the treatment of human immunodeficiency virus (HIV-1) infection in treatment-experienced and treatment-naïve patients with no darunavir resistance-associated mutations[i].[1] Darunavir is always taken in combination with ritonavir and other HIV medicines together with food. This new tablet strength has been developed to allow patients taking darunavir once daily to reduce the number of darunavir tablets by half.

The approval is based on study C176[2] which evaluated the 400 mg tablet formulation versus the 800 mg formulation. One hundred and twenty eight healthy volunteers, were included in this study and received treatment under fasting (n=83) or under fed conditions (n=45). The results of this study show that the rate and extent of absorption were similar between intake of a single 800 mg dose of darunavir formulated as one 800 mg tablet or two 400 mg tablets.[2]

"Strict adherence to treatment regimens is crucial to prevent virological failure and the development of drug resistance when treating HIV," said Brian Woodfall, Vice President, Medical Affairs, Janssen EMEA. "This single 800 mg tablet formulation is a direct reflection of the ongoing commitment of Janssen to

[i] ART-experienced adults with no darunavir resistance associated mutations (DRV-RAMs) and who have plasma HIV-1 RNA < 100,000 copies/ml and CD4+ cell count ≥ 100 cells x 10^6/l.

further develop treatment options for people living with HIV. With this approval we are providing an alternative solution and a reduced pill burden which should make it easier for patients to manage their treatment on a day-by-day basis and keep their HIV at undetectable levels."

It is estimated that currently there are 34.5 million people living with HIV globally, with 2.5 million people becoming newly infected each year.[3] Thanks to significant advances in treatment for HIV over the past 30 years a diagnosis for these people is no longer a death sentence. Yet, data shows that after 8 months of treatment only 65% of patients will achieve 100% compliance.[4] Missing doses can allow drug levels in the blood to fall which could allow viral replication to occur and greatly increase the risk of resistance emerging.[5]

-Ends-

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 patients as well as antiretroviral therapy (ART) experienced 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)[ii] 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

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

trials and as spontaneous reports are diarrhoea, immune reconstitution syndrome, nausea, pyrexia and rash. The most frequent serious reactions are diarrhoea, hepatitis, immune reconstitution syndrome, pyrexia and rash. 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 in HIV - Commitment to Innovative Research & Development

Over the last five years, Janssen has launched three therapies for people living with HIV. Janssen has a long heritage in HIV and is committed to innovation in HIV therapies. Janssen is constantly striving for improvements in efficacy, safety and dosing simplification and is committed to evaluating HIV treatments for a broad range of patients—from treatment-naïve to treatment-experienced—with the goal of helping all patients achieve an undetectable viral load and a better quality of life.

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

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1. PREZISTA 800 mg. Summary of Product Characteristics, 2012.
2. Janssen data on file.

3. World Health Organization. Global summary of the AIDS epidemic. Available at URL: http://www.who.int/hiv/data/2012_epi_core_en.png . Last accessed December 3, 2012.
4. Mannheimer S, Friedland G, Matts J, et al. The consistency of adherence to antiretroviral therapy predicts biologic outcomes for human immunodeficiency virus-infected persons in clinical trials. Clinical Infectious Diseases. 2002; 34:1115-1121.
5. Aids Map. Adherence. Available at URL: http://www.aidsmap.com/Adherence/page/1730785/. Last accessed December 3, 2012.