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EUROPEAN COMMISSION APPROVES REZOLSTA®▼, A NEW ONCE-DAILY, FIXED-DOSE HIV THERAPY COMBINING DARUNAVIR AND COBICISTAT

Approval marks another step towards improving the lives of people living with HIV

Beerse, Belgium, 25 November 2014 – Janssen-Cilag International NV (Janssen) today announced that the European Commission (EC) has approved the use of REZOLSTA® (darunavir/cobicistat) in combination with other antiretroviral (ARV) medicinal products for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults aged 18 years or older.

The decision from the EC follows a Positive Opinion recommending the use of REZOLSTA® from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in September 2014.[1] At that time, the CHMP also announced two label indication extensions for darunavir, a protease inhibitor marketed as PREZISTA® by Janssen, which have also been approved by the EC.[2,3]

REZOLSTA® is a new once-daily, fixed-dose combination tablet containing darunavir and the pharmacokinetic enhancing or "boosting" agent cobicistat (marketed as Tybost™ by Gilead Sciences, Inc.). The Janssen marketing authorization application was based on bioequivalence data evaluating the use of a darunavir and cobicistat fixed-dose combination tablet versus single agents,[4] and a clinical study evaluating the safety and efficacy of cobicistat-boosted darunavir for the treatment of HIV-1 in adults with no darunavir resistance-associated mutations.[5] The tolerability profile of the fixed dose-combination is similar to that of the two agents taken separately.[4]

"This approval can be seen as another step forward for patients living with and receiving treatment for HIV," said Christiane Moecklinghoff, M.D Ph.D, Medical Director, Virology, Janssen EMEA. "Progress in the development of effective treatments is helping people with HIV to live longer, but treatment regimens can still impact daily life. REZOLSTA® eliminates the need to take a boosting agent in a separate tablet with once-daily darunavir, reducing the pill burden for patients."

The two additional label indication extensions relating to darunavir approved by the EC, will now be implemented across Europe in line with local regulatory bodies. s allows a once-daily dosing regimen of darunavir in children within this age group, adding to increased convenience in this pediatric population. The second label indication extension is for cobicistat as an alternate booster for darunavir in adults aged 18 years or older in combination with other ARVs,[3] providing another booster option for darunavir in people living with HIV.

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The darunavir and cobicistat fixed-dose combination was approved in Canada in June 2014 under the name PREZCOBIX™, and is currently undergoing regulatory review by the FDA in the USA.

Janssen will continue to make darunavir available, as a single agent in tablets, so patients and their physicians can decide which treatment regimen is best for them.

About HIV
Since the beginning of the HIV epidemic, almost 75 million people have been infected with the HIV virus.[6] It is estimated that 35 million people are currently living with HIV globally, with 2.5 million people becoming newly infected each year.[6,7]

About PREZISTA® (darunavir)
Darunavir is a protease inhibitor used for the treatment of human immunodeficiency virus (HIV-1) infection and can be taken with either ritonavir (indicated for use in adults and pediatric patients from the age of 3) or cobicistat (indicated for use in adults only).[3] Darunavir received initial approval in Europe in 2007 for use in HIV-1 infected highly pre-treated patients, with later approvals for treatment-naïve and less experienced adult patients, and then for use in pediatric patients. Darunavir/ritonavir is approved for use in pediatric patients aged 3-17.

About Tybost™ (cobicistat)
Tybost (cobicistat 150 mg tablets) is a cytochrome P450 3A (CYP3A) inhibitor. It boosts blood levels of atazanavir or darunavir by suppressing CYP3A, an enzyme that metabolises these drugs in the body. Cobicistat acts only as a pharmacokinetic enhancer and has no antiviral activity.[8] Cobicistat was developed by Gilead and is a pharmacokinetic enhancer or boosting agent used with the protease inhibitors darunavir and atazanavir for the treatment of HIV, and is also found in STRIBILD® (elvitegravir / cobicistat / emtricitabine / tenofovir). Gilead is responsible for the manufacture, development and commercialization of cobicistat as a stand-alone product.

About Janssen in HIV
Janssen is committed to research and development of medicines to treat HIV infections; combat resistance; simplify treatment; discover, develop, and conduct early basic research toward fulfilling the dream of a HIV vaccine.

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.

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