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Janssen Submits Marketing Authorisation Application for Darunavir-Based Single Tablet Regimen for Treatment of HIV-1 to European Medicines Agency

Beerse, Belgium, 12 September 2016 – Janssen-Cilag International NV (Janssen) today announced the submission of a Marketing Authorisation Application to the European Medicines Agency (EMA), seeking approval for a new once-daily darunavir-based single tablet regimen (STR). If approved, this tablet would be the first protease inhibitor (PI)-based STR option (D/C/F/TAF FDC), indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and adolescents (aged 12 years and older with body weight of at least 40 kg). This new treatment would combine the protease inhibitor, darunavir (DRV, D, 800 mg), with the pharmacokinetic enhancer, cobicistat (COBI, C, 150 mg) and the nucleoside reverse transcriptase inhibitors emtricitabine (FTC, F, 200 mg) and tenofovir alafenamide (TAF 10 mg), in one single tablet.

Treatment regimens that combine DRV/COBI (REZOLSTA®, Janssen-Cilag International NV) and F/TAF (Gilead Sciences International Ltd) are currently approved[1,2] for the maintenance treatment of HIV. The darunavir STR option is a significant evolution of this approach, combining both treatments in a single, convenient tablet.

"Darunavir is an extensively used HIV protease inhibitor in the European Union. We are excited to take this important step in our efforts to offer simpler solutions for people living with HIV," said Lawrence M. Blatt, Ph.D., global therapeutic area head, Janssen Infectious Diseases and Vaccines, and president and chief executive officer of Alios BioPharma, Inc. *"Progress in the development of effective treatments is helping people with HIV to live longer, but treatment regimens can still impact daily life. Eliminating the need for separate tablets will not only be convenient for people living with HIV but is likely to lead to improved treatment adherence."*

On 29 December 2014, Janssen announced a license agreement with Gilead for the development and commercialisation of a once daily STR combination of darunavir and Gilead's cobicistat, emtricitabine and tenofovir alafenamide. Under the terms of the agreement, Janssen and its affiliates are responsible for the manufacturing, registration, distribution and commercialisation of this STR worldwide. Gilead retains sole rights for the

manufacturing, development and commercialisation of cobicistat, emtricitabine and tenofovir alafenamide as stand-alone products, and for use in combination with other agents.

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About HIV
Since the beginning of the HIV epidemic, almost 70 million people worldwide have been infected with the HIV virus.[3] It is estimated that 36.7 million people are currently living with HIV globally.[3] HIV transmission is a major concern in Europe, in particular in the eastern part of the WHO European Region. In 2014, more than 142,000 people were diagnosed with HIV - the highest number of newly diagnosed infections ever reported in one year.[4] Of these, 77% were diagnosed in the East of the Region and 21% in the EU/EEA.[4]

More data on HIV is available at the DiseaseLens™ platform which aggregates, besides 19 other diseases, the HIV disease burden public data in one place and allows to compare them among 31 countries in Europe and Israel:
http://www.diseaselens.com/v2/disease.php?disease=5 -
https://www.youtube.com/watch?v=PtzR8TfoKfk"

About PREZISTA® (darunavir)
PREZISTA, 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.

PREZISTA, co-administered with cobicistat is indicated in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients.

In deciding to initiate treatment with PREZISTA co-administered with cobicistat or low dose ritonavir, careful consideration should be given to the treatment history of the individual patient and the patterns of mutations associated with different agents. Genotypic or phenotypic testing (when available) and treatment history should guide the use of PREZISTA.

About REZOLSTA® (darunavir/cobicistat)
REZOLSTA is an antiviral medicine used, in combination with other medicines, to treat adults with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). REZOLSTA contains the active substances darunavir and cobicistat. The medicine is for use only in patients who have not received HIV treatment before or previously treated patients whose disease is not expected to be resistant to darunavir and who are healthy enough and have HIV virus levels below a certain threshold.

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

About the Janssen Pharmaceutical Companies of Johnson and Johnson
At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at http://www.janssen.com/emea. Follow us at www.twitter.com/janssenEMEA.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development of treatment options for HIV-1. 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 known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product development, including uncertainty of clinical success and obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in Exhibit 99 thereto, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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