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Janssen Receives Positive CHMP Opinion for SYMTUZA™ The First Darunavir-Based Single-Tablet Regimen for the Treatment of HIV

- *Proven efficacy and durability of darunavir combined with the improved renal laboratory and bone mineral density profile of emtricitabine/tenofovir alafenamide as compared to emtricitabine/tenofovir disoproxil fumarate into one single tablet*

Beerse, Belgium, 21 July 2017 – Janssen-Cilag International NV (Janssen) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a Positive Opinion recommending marketing authorisation for SYMTUZA™ (darunavir/cobicistat/emtricitabine/tenofovir alafenamide [D/C/F/TAF]), a once-daily darunavir-based single tablet regimen (STR).

If approved, it will be the only darunavir-based STR indicated 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, with genotypic testing guiding use. This STR combines the proven efficacy and durability of darunavir with the improved renal laboratory and bone mineral density profile of F/TAF as compared to F/TDF (tenofovir disoproxil fumarate), and will be the only treatment that could deliver the adherence advantages of a STR coupled with the high genetic barrier to resistance that darunavir offers.

"Darunavir is one of the most widely used HIV treatments in the European Union due to its ability to control the HIV virus while offering a high barrier to resistance. We will now be able to combine a complete darunavir-based HIV treatment regimen into a once daily tablet. We are extremely excited to be one step closer to getting this therapy to people

living with HIV and in doing so hope to reduce the treatment burden faced by many living with the virus," said Lawrence M. Blatt, Ph.D., Global Therapeutic Area Head, Janssen Infectious Diseases Therapeutics.

"A darunavir-based STR represents a significant evolution in treatment options for HIV patients," said Jean-Michel Molina, Professor of Infectious Diseases at the University of Paris Diderot. "With around two million people in Europe currently managing their HIV, this is a true advancement in helping patients achieve an undetectable viral load and improving quality of life. Reducing the pill burden allows people greater freedom and flexibility, and through this we may also improve treatment adherence."

The Positive Opinion is based on a bioequivalence study comparing the once-daily STR with the combined administration of the separate agents darunavir [D] 800 mg, cobicistat [C] 150 mg, and emtricitabine/tenofovir alafenamide [FTC/TAF] 200 mg/10 mg fixed-dose combination. A Phase 3 clinical trial programme investigating the efficacy and safety of the darunavir-based combination is underway. Data on the bioequivalence study, as well as interim data from the Phase 3 Pivotal EMERALD trial in virologically suppressed antiretroviral therapy (ART) experienced patients, who were switched to the STR, will be presented at the upcoming International AIDS Society (IAS) conference in Paris, France. Further EMERALD 48-week data, and 48-week data from the Phase 3 AMBER trial in ART naïve patients, will be released in due course. Please visit www.jnj.com/HIV for further details on the breadth of science being presented by Johnson & Johnson companies and its partners.

The CHMP's Positive Opinion will now be reviewed by the European Commission, which has the authority to grant marketing authorisation for medicines in the European Economic Area. The European Commission's final decision is anticipated in the coming months.

Janssen have brought medicines to market across a range of patient populations that have helped to transform the efficacy and tolerability of treatment. Treatment regimens that combine D/C (REZOLSTA®, Janssen-Cilag International NV, U.S name PREZCOBIX®) and F/TAF (DESCOVY®, Gilead Sciences International Ltd) are currently approved[1,2] for the treatment of HIV. SYMTUZA™ is a significant evolution of this approach, combining both treatments in a single, convenient tablet, and is part of Janssen's broader commitment to develop effective and innovative therapies which address the issues of adherence and resistance.

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Notes to editors

On 23 December 2014, Janssen and Gilead Sciences International Ltd amended a licensing agreement for the development and commercialisation of a once-daily STR combination of darunavir and Gilead's TAF, emtricitabine and cobicistat. Under the terms of the agreement, Janssen and its affiliates are responsible for the manufacturing, registration, distribution and commercialisation of this STR worldwide.

About Janssen

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 www.janssen.com/emea/ and follow us at @JanssenEMEA.

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). 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.

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 potential preventive and treatment regimens for HIV. 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 the Janssen Pharmaceutical Companies and 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; uncertainty of commercial success for new indications and therapeutic combinations; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behaviour and spending patterns of purchasers of health care products and services; 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 Annual Report on Form 10-K for the year ended January 1, 2017, including under "Item 1A Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including in the section captioned "Cautionary Note Regarding Forward-Looking Statements," 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.

References:

1. European Medicines Agency: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002819/human_med_001817.jsp&mid=WC0b01ac058001d124 Last accessed June 2017.

2 . European Medicines Agency: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004094/human_med_001978.jsp&mid=WC0b01ac058001d124 Last accessed June 2017.