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European Commission Approves Symtuza® for the Treatment of HIV-1 In Adults and Adolescents in Europe

- *Symtuza® is the only darunavir-based single-tablet regimen (STR) approved for the treatment of HIV-1 in the European Union*

Beerse, Belgium, 26 September 2017 – Janssen-Cilag International NV (Janssen) today announced that the European Commission has approved the use of Symtuza® (darunavir/cobicistat/emtricitabine/tenofovir alafenamide [D/C/F/TAF])[1], a once-daily darunavir-based single-tablet regimen (STR), 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. Cobicistat, emtricitabine and tenofovir alafenamide are from Gilead Sciences, Inc.

The only darunavir-based STR indicated for the treatment of this patient group, Symtuza® 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 (emtricitabine/tenofovir disoproxil fumarate). It is the only approved treatment to offer the convenience of an STR alongside the high genetic barrier to resistance provided by darunavir.

“There are almost one million people in the European Union currently living with HIV. The availability of a single-treatment regimen with a high barrier to resistance mutations eliminates the need for separate tablets, reducing the burden of pills on daily life for patients, and helping them to achieve improved treatment adherence and viral suppression,” said Jean-Michel Molina, Professor of Infectious Diseases at the University of Paris Diderot.

"At Janssen, we are committed to developing effective and innovative treatments which address the issues of adherence and resistance. Today's approval by the European Commission demonstrates our efforts to treat HIV more simply, helping all those living with HIV to achieve an undetectable viral load while enjoying an improved quality of life," said Lawrence M. Blatt, Ph.D., Global Therapeutic Area Head, Janssen Infectious Diseases Therapeutics.

Results from a bioequivalence study that compared Symtuza® 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 were presented at the International AIDS Society (IAS) conference in Paris, France in July.[2] These results confirmed that the once-daily STR is bioequivalent to the combined administration of the separate agents, as well as demonstrating that the STR is well tolerated.

In addition, results from the pivotal Phase 3 EMERALD study presented at IAS showed that the once-daily STR containing darunavir 800 mg, cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide 10 mg [D/C/F/TAF] had a low cumulative virologic rebound rate and a high virologic suppression rate at 24 weeks in HIV-1 positive, virologically suppressed adults who switched from a standard boosted protease inhibitor (PI) plus tenofovir/emtricitabine regimen. A Phase 3 clinical trial programme investigating the efficacy and safety of the darunavir-based combination is ongoing. In October, EMERALD 48-week data will be presented at ID Week 2017 in San Diego, California, USA, and 48-week data from the Phase 3 AMBER trial in antiretroviral therapy (ART) naïve patients will be presented at the European AIDS Clinical Society (EACS) Conference in Milan, Italy.[3,4]

On 20 July, the European Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion for Symtuza®.[5] This subsequent European Commission approval allows Janssen to market Symtuza® in all countries in the European Union and European Economic Area.[1]

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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 Symtuza®

In the European Union, Symtuza® is 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 at least 40 kg). Genotypic testing should guide the use of Symtuza®.

Symtuza® is a fixed-dose combination of four active substances (darunavir, cobicistat, emtricitabine and tenofovir alafenamide), available as 800 mg/150 mg/200 mg/10 mg film-coated tablets. Darunavir inhibits the HIV protease and prevents the formation of mature infectious virus particles. Emtricitabine and tenofovir alafenamide are substrates and competitive inhibitors of HIV reverse transcriptase. After phosphorylation, they are incorporated into the viral DNA chain, resulting in chain termination. Cobicistat enhances the systemic exposure of darunavir and has no direct antiviral effect.

About the Janssen Pharmaceutical Companies of Johnson & 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 www.janssen.com/emea/ and follow us at @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 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.

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[1] European Medicines Agency
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004391/smops/Positive/human_smop_001176.jsp&mid=WC0b01ac058001d127

[2] 9th IAS Conference on HIV Science 2017
http://www.ias2017.org/Portals/1/Files/IAS2017_LO.compressed.pdf?ver=2017-07-27-211231-197

[3] ID Week 2017 https://idsa.confex.com/idsa/2017/webprogram/start.html

[4] 16th European AIDS Conference http://www.eacs-conference2017.com/index.php?article_id=147

[5] European Medicines Agency, Symtuza Summary of opinion
http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion_-_Initial_authorisation/human/004391/WC500231710.pdf