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Janssen's New Darunavir-Based Single Tablet Regimen SYMTUZA® Shows Positive Outcome in Treatment of Antiretroviral-Naïve HIV Patients

Once-daily single tablet complete regimen demonstrates effective viral suppression in HIV-1 patients, providing a genetic barrier to the development of resistance with a favourable safety profile

Milan, Italy, 25 October 2017 – Janssen's new once-daily, single tablet combination therapy SYMTUZA® (darunavir/cobicistat/emtricitabine/tenofovir alafenamide [D/C/F/TAF]) has shown to be both highly effective and well-tolerated in treating antiretroviral-naïve HIV-1 patients through 48 weeks in the pivotal phase 3 AMBER study[1]. The results of this study will be presented on 27 October 2017 at the 16th European AIDS Conference (EACS) in Milan, Italy.

Findings from the study demonstrated that the single tablet regimen (STR) D/C/F/TAF provided effective and durable viral suppression, meaning most patients achieved an undetectable viral load, whilst offering the high genetic barrier to resistance of darunavir, for ART-naïve HIV-1-infected patients.[1]

"The AMBER study results show that the boosted darunavir-based STR which also contains F/TAF was a highly effective regimen with favourable kidney and bone safety laboratory parameters compared to F/TDF (emtricitabine/tenofovir disoproxil fumarate). It was very well-tolerated, and doses in a single daily tablet," said Chloe Orkin, Chair of the British HIV Association (BHIVA) and Consultant Physician at the Royal London Hospital.

AMBER is a Phase 3 randomised double-blind non-inferiority international study designed to assess the efficacy and safety of D/C/F/TAF versus the control in HIV-1 positive treatment-naïve adult patients over 48 weeks. The control comprised two separate medications – a tablet of darunavir/ cobicistat (D/C) plus a tablet of emtricitabine/ tenofovir disoproxil fumarate (F/TDF). The primary endpoint was non-inferiority of the

STR versus the control regarding the proportion of patients with a viral load (VL) of less than 50 copies per mL at 48 weeks (per FDA snapshot analysis).[1] Reducing their viral load to an undetectable level is a key treatment goal for HIV patients, enabling their immune system to strengthen and leading to improved quality of life.[2]

The single tablet D/C/F/TAF demonstrated durable non-inferiority versus the control group over 48 weeks (HIV RNA <50 c/ml 91.4% vs 88.4% respectively, difference 2.7%; 95% CI: −1.6 to 7.1) and also produced low virologic failure rates (VL≥50 c/mL; FDA-Snapshot: 4.4% (16/362) versus 3.3% (12/363)).[1] The high efficacy results were consistent across different subgroups of patients. No treatment-emergent mutations related to darunavir, primary protease inhibitors or tenofovir (TFV) were observed. The STR showed improved bone and renal safety laboratory parameters, along with similar safety versus control through 48 weeks, in terms of rates of discontinuations due to adverse events (AEs – 1.9% vs. 4.4%), of Grade 3-4 AEs (5.2% vs 6.1%), and of serious AEs (4.7% vs. 5.8%).[1] D/C/F/TAF also demonstrated a similar total cholesterol/HDL cholesterol ratio, with limited lipid changes.[1]

D/C/F/TAF safety and efficacy were also demonstrated in the open label Phase 3 48-week EMERALD study, a switch trial amongst virologically suppressed ART experienced patients.[3]

"Janssen's mission in HIV is the delivery of transformational innovations to meet the diverse needs of the HIV community and to offer simple yet effective solutions to reduce the burden on those affected by this disease. The recent European approval of D/C/F/TAF coupled with the AMBER results mean that we can offer the community a new treatment option, highly effective at achieving viral suppression, for HIV-1 patients about to embark on their first antiretroviral therapy," said Brian Woodfall, MD, Global Head of Late Development, Infectious Diseases and Vaccines, Janssen.

D/C/F/TAF is the first once-daily darunavir-based single-tablet regimen (STR), and recently received European Commission approval on 21 September 2017.[4] In the U.S., D/C/F/TAF is an investigational product and has not been proven to be safe or efficacious. A new drug application (NDA) was filed on 22 September 2017 with the U.S. Food and Drug Administration (FDA) and is currently awaiting approval.[5]

D/C/F/TAF has been developed by Janssen to provide HIV patients with a convenient once-daily, single tablet that provides highly effective viral suppression through the combined action of darunavir, cobicistat, emtricitabine and tenofovir alafenamide. Furthermore, the new STR comes with the high genetic barrier to viral resistance

development provided by darunavir and the favourable renal and bone safety profile seen with tenofovir alafenamide.[3]

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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 a body weight at least 40 kg). Genotypic testing should guide the use of SYMTUZA®.[6]

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.[6]

About the AMBER trial

AMBER is a Phase 3, randomised, active-controlled, double-blind, international, multicentre, parallel-group, non-inferiority study. Subjects were randomly assigned (362 D/C/F/TAF and 363 control) and treated. The primary endpoint was non-inferiority of D/C/F/TAF versus control regarding the proportion of patients with viral load [VL] <50 copies per mL (FDA-snapshot analysis) at 48 weeks (10% margin).[1]

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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