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Janssen Presents Positive Long-Term Efficacy and Safety of SYMTUZA®▼ (D/C/F/TAF) in Treatment-Naïve Adults with HIV-1

New Phase 3 AMBER study data continues to demonstrate high rates of virologic suppression at 96 weeks in ART-naïve adults with HIV-1 when treated with D/C/F/TAF[1]

Glasgow, UK, 30 October 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson today unveiled 96-week results from the pivotal Phase 3 AMBER study of SYMTUZA® (darunavir 800 mg, cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide 10 mg (D/C/F/TAF)) at HIV Glasgow in Scotland. D/C/F/TAF is 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. Genotypic testing should guide the use of D/C/F/TAF.[2]

Results from the AMBER study demonstrated that a high proportion of antiretroviral treatment (ART)-naïve adults with HIV-1 (85%, 308/362) maintained virologic suppression (viral load <50c/mL; FDA-snapshot) at 96 weeks when treated with D/C/F/TAF. No darunavir, primary protease inhibitor, or tenofovir resistance-associated mutations emerged in any patient. As previously reported, only one patient receiving D/C/F/TAF developed a nucleoside reverse transcriptase inhibitor resistance-associated mutation (M184V) through week 48. In the current analysis through 96 weeks, only one additional patient receiving D/C/F/TAF developed a nucleoside reverse transcriptase inhibitor resistance-associated mutation to emtricitabine (M184V).[1]

These 96-week data, which follow on from the earlier 48-week results,[3] reinforce the long-term efficacy, high genetic barrier and safety of D/C/F/TAF as a treatment for ART-naïve adults with HIV-1.[1] The control arm of the study consisted of 512 patient years exposure to darunavir (D)+ cobicistat (C)+ emtricitabine (F)/ tenofovir disoproxil fumarate (TDF) and 109 patient years exposure to D/C/F/TAF.[1]

"The 96-week results from the AMBER study demonstrate that the darunavir-based single-tablet regimen has a good safety profile and efficacy and a high genetic barrier beyond the first year of treatment. The regimen adds to the choices for patients who start and receive life-long HIV therapy," said Professor Chloe Orkin, Lead for HIV research at Barts Health NHS Trust.

D/C/F/TAF was generally well-tolerated with 3% (10/362) adverse event (AE)-related discontinuations over 96 weeks and 3% (11/362) of people experiencing a grade 3 or 4 study-drug related AE, compared with 1% (3/295) in the comparator arm. Bone, renal and lipid safety were consistent with known tenofovir alafenamide and cobicistat profiles.[1] Efficacy and safety results were consistent with the 48-week results in the D/C/F/TAF group.[1]

"These results mark another important milestone in ensuring that individualised treatment options are available to those living with HIV-1," said Kimberley Brown, PharmD, AAHIVE, Study Responsible Scientist, Janssen Research & Development, LLC. "At Janssen, we are building on our 25-year heritage in HIV and remain committed to ongoing research and development of innovative solutions with the aim to make HIV history."

On September 26, 2017, D/C/F/TAF was approved for the treatment of HIV-1 infection by the European Commission,[4] based on results from a bioequivalence study that compared D/C/F/TAF 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.[5] US FDA approval was granted on July 17, 2018[6] based on the results from the two pivotal Phase 3 studies, EMERALD and AMBER.[3,7]

96-week results from the Phase 3 EMERALD trial in treatment-experienced virologically suppressed adults with HIV-1 were recently presented at IDWeek 2018, in San Francisco, CA.[8]

D/C/F/TAF does not cure or prevent HIV-1 or AIDS.

ENDS

Notes to editors

About the AMBER clinical trial[1,3]

AMBER is a Phase 3 randomised, double-blind, active-controlled, international, multi-centre, non-inferiority study designed to assess the safety and efficacy of D/C/F/TAF versus the control in HIV-1 treatment-naïve patients at Week 48, and the long-term efficacy and safety of D/C/F/TAF at Week 96. The control was comprised of two separate medications – darunavir/cobicistat plus emtricitabine 200mg/tenofovir disoproxil fumarate 300mg – and patients were randomly assigned (362 D/C/F/TAF; 363 control). Based on the results of the primary analysis all patients, after unblinding, received treatment with D/C/F/TAF during an open-label single group treatment phased up to Week 96. The primary endpoint was non-inferiority of the single-tablet regimen versus the control regarding the proportion of patients that achieved viral suppression (viral load of less than 50 c/mL at 48 weeks – per FDA snapshot analysis). Reaching suppression of viral load (or the amount of HIV virus in the blood) is a key treatment goal for people living with HIV-1. FDA snapshot efficacy outcomes were also reported.[1]

48-week data have been previously reported.[3] At Week 96, of the 725 patients treated, a high proportion of patients in the D/C/F/TAF arm (85%, 308/362) maintained virologic suppression (viral load of <50c/mL – per FDA Snapshot analysis), compared to 88% (321/363) in the comparator arm. Viral load of ≥50c/mL per the FDA Snapshot at Week 96 occurred in 20/362 (6%) patients in the D/C/F/TAF arm, compared to 3% (12/363) in the control arm. No darunavir, primary protease inhibitor, or tenofovir resistance-associations emerged in any patient. Through 96 weeks, only two patients receiving D/C/F/TAF developed a nucleoside reverse transcriptase inhibitor resistance-associated mutation to emtricitabine (M184V).[1] D/C/F/TAF was generally well-tolerated with few serious adverse events. 11% (39/362) of patients experienced serious adverse events and 3% (10/362) experienced adverse event-related discontinuations. No deaths occurred. In the comparator arm, 3% (8/295) of patients experienced serious adverse events and 1% (<1/295) experienced adverse event-related discontinuations. Bone, renal and lipid safety were consistent with known tenofovir and

cobicistat profiles, with a small change in TC/HDL-C ratio.[1] Efficacy and safety results were consistent with the 48-week results seen in the D/C/F/TAF arm.[1]

Cobicistat, emtricitabine and tenofovir alafenamide are from Gilead Sciences, Inc. On December 23, 2014, Janssen and Gilead Sciences Inc. amended a licensing agreement for the development and commercialisation of a once-daily single-tablet regimen 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 single-tablet regimen worldwide.

About D/C/F/TAF[2]
In the European Union, D/C/F/TAF 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 D/C/F/TAF.[2]

D/C/F/TAF 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.[2]

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. Janssen-Cilag International NV and Janssen Research & Development, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Prescribing and safety information
For important prescribing and safety information for D/C/F/TAF in the European Union please visit: www.ema.europa.eu/en/medicines/human/EPAR/symtuza

For complete prescribing and safety information in the UK, please visit: www.medicines.org.uk/emc/product/8430

▼Adverse events should be reported. This medicinal product is subject to additional monitoring and it is therefore important to report any suspected adverse events related to this medicinal product. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Janssen-Cilag Ltd on 01494 567447 or at dsafety@its.jnj.com.

References

[1] Orkin C, Eron JJ, Rockstroh J, *et al.* Efficacy and safety of the once-daily, darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) single-tablet regimen (STR) in antiretroviral treatment (ART)-naïve, HIV-1-infected adults: AMBER Week 96 results. Presented at HIV Glasgow 2018, Glasgow, October 28-31,; abstract O212. Available at: https://onlinelibrary.wiley.com/doi/full/10.1002/jia2.25187. Last accessed October 2018.

[2] Symtuza 800 mg/150 mg/200 mg/10 mg film-coated tablets. Summary of product characteristics. Janssen-Cilag Ltd. Last updated 27 Sept 2018. Available at: www.medicines.org.uk/emc/product/8430/smpc Last accessed October 2018

[3] Gallant J, *et al.* Week 48 results of AMBER: a phase 3, randomised, double-blind trial in antiretroviral treatment (ART)-naïve HIV-1-infected adults to evaluate the efficacy and safety of the once-daily, single-tablet regimen (STR) of darunavir/ cobicistat/ emtricitabine/ tenofovir alafenamide (D/C/F/TAF) versus darunavir/cobicistat (DRV/c) plus emtricitabine/ tenofovir disoproxil fumarate (FTC/TDF). Presented at the European AIDS Clinical Society Conference 2017. Milan, October 25-27, 2017; abstract PS8/2. Available at: www.abstractserver.com/eacsabstractarchive/ Last accessed October 2018.

[4] Janssen. European Commission approves Symtuza® for the treatment of HIV-1 in adults and adolescents in Europe. Press release 26 September 2017. Available at: www.jnj.com/media-center/press-releases/european-commission-approves-symtuza-for-the-treatment-of-hiv-1-in-adults-and-adolescents-in-europe Last accessed October 2018.

[5] Crauwels H, *et al*. Bioequivalence of a darunavir-based single-tablet complete HIV-1 regimen compared to the separate agents. Presented at 9th IAS Conference on HIV Science 2017; abstract MOPEB0335. Available at: http://programme.ias2017.org/Abstract/Print/?abstractid=4016 Last accessed: October 2018.

[6] Janssen. Janssen announces U.S. FDA approval of SYMTUZA (D/C/F/TAF), the first and only complete darunavir-based single-tablet regimen for the treatment of HIV-1 infection. Press release July 17, 2018. Available at: www.janssen.com/janssen-announces-us-fda-approval-symtuza-dcftaf-first-and-only-complete-darunavir-based-single-0 Last accessed October 2018.

[7] Molina JM, *et al.* Efficacy and safety of switching from boosted-protease inhibitor plus emtricitabine/tenofovir disoproxil fumarate regimens to the single-tablet regimen of darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) in virologically-suppressed, HIV-1-infected adults through 24 weeks: EMERALD study. Presented at 9th IAS Conference on HIV Science 2017; abstract TUAB0101. Available at: http://programme.ias2017.org/Abstract/Abstract/4194 Last accessed: October 2018.

[8] Eron J, *et al*. Efficacy and safety of switching from boosted-protease inhibitors (bPI) plus emtricitabine/tenofovir disoproxil fumarate (F/TDF) regimens to the once daily (QD), single-tablet regimen (STR) of darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) in virologically-suppressed, HIV-1-infected adults: week 96 results of the phase 3, randomized, non-inferiority EMERALD trial. Presented at IDWeek 2018, San Francisco, CA, USA, October 3-7, 2018; abstract 1768. Available at: https://idsa.confex.com/idsa/2018/webprogram/Paper72755.html Last accessed October 2018.