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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

- SYMTUZA™ (darunavir 800 mg, cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide 10 mg) offers new treatment option for adults living with HIV-1 infection
- Once daily, single-tablet regimen delivers the durability and high barrier to drug resistance of darunavir and the safety profile of tenofovir alafenamide (TAF)

TITUSVILLE, N.J, JULY 17, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the U.S. Food and Drug Administration (FDA) has approved SYMTUZA™, the first and only complete, darunavir-based single-tablet regimen (STR) for the treatment of human immunodeficiency virus type 1 (HIV-1) in treatment-naïve and certain virologically suppressed adults. SYMTUZA™ combines the proven high barrier to resistance of darunavir with a formulation designed for improved tolerability and the convenience of an STR. SYMTUZA™ has a Boxed Warning regarding the risk of post-treatment acute exacerbation of hepatitis B. See below for Important Safety Information.

[Click to Tweet](#) #NEWS: FDA approves new @JanssenUS treatment for HIV. Read full press release here: <http://po.st/LK3iIr>

[Click to Tweet](#) @JanssenUS announces #FDA approval for SYMTUZA. See full PI incl Boxed Warning: <http://po.st/kuzDlq>

“As clinicians, we may not always have the full picture of a patient’s health or their risk for developing resistance when making treatment decisions. In key Phase 3 clinical trials, SYMTUZA™ successfully treated those who were starting therapy, as well as those who were stably suppressed on antiretroviral (ARV) therapy – including patients with more complex treatment histories or previous virologic failure – demonstrating its potential as an important new treatment option for a wide variety of patients,” said Joseph Eron, M.D., Professor of Medicine and Director, Clinical Core, University of North Carolina Center for AIDS Research, Chapel Hill, N.C.

The U.S. Department of Health and Human Services guidelines¹ recommend darunavir-based therapies for treatment-naïve patients in certain clinical situations, including when a person may have uncertain adherence or when ARV treatment should be initiated before resistance test results are available.

“Many people living with HIV struggle to adhere to their medication, which can lead to the development of drug resistance and potentially cause their medication – or even an entire class of medications – to stop working,” continued Dr. Eron.

SYMTUZA™ received FDA approval based on data from two 48-week, non-inferiority, pivotal Phase 3 studies that assessed the safety and efficacy of SYMTUZA™ versus a control regimen in adults with no prior ARV history (AMBER) and in virologically suppressed adults (EMERALD). Results from both trials demonstrated that SYMTUZA™ was effective and well-tolerated, with up to 95 percent achieving or maintaining virologic suppression (HIV-1 RNA <50c/mL).

- AMBER compared SYMTUZA™ to darunavir/cobicistat (D/C) plus emtricitabine/tenofovir disoproxil fumarate (F/TDF). The results, presented at the 16th European AIDS Conference in October 2017, demonstrated similar viral suppression rates (HIV-1 RNA <50c/mL at 48 weeks – per FDA Snapshot analysis) between the darunavir-based STR vs. control (91.4% vs 88.4% respectively) and low virologic failure rates (HIV-1 RNA ≥50 c/mL; 4.4% vs. 3.3%) at 48 weeks. SYMTUZA™ also showed less bone loss (in a sub-study) and a significant improvement in markers of renal function versus control. The long-term clinical significance of these bone mineral density (BMD) changes is not known. Overall, SYMTUZA™ was well-tolerated, with fewer discontinuations due to an adverse event

(AE; 2% vs. 4%) versus control, only one grade 3 adverse reaction and no grade 4 adverse reactions. The most frequent adverse reactions reported in $\geq 2\%$ of subjects were diarrhea, rash, nausea, fatigue, headache, abdominal discomfort and flatulence.

- The EMERALD study, presented at IDWeek in October 2017, compared SYMTUZA™ to continuing treatment with a boosted protease inhibitor (bPI) plus emtricitabine and TDF. The trial found there were low virologic failure rates (HIV-1 RNA ≥ 50 c/mL; 0.8% vs. 0.5%) and high virologic suppression rates (HIV-1 RNA < 50 c/mL; 94.9% vs. 93.7%) according to FDA Snapshot analysis at Week 48, with no patients discontinuing the study due to virologic failure. Switching to SYMTUZA™ demonstrated improvement in BMD (in a sub-study) and a significant improvement in some markers of renal function versus control. The long-term clinical significance of these BMD changes is not known. The safety profile was similar to that of those patients with no prior ARV treatment history, and the percentage of participants who discontinued due to AEs, regardless of severity, was 1%.

“For more than 25 years, Janssen has been committed to the research and development of transformational medical innovation across the continuum of HIV care. The FDA approval of SYMTUZA™ marks another important milestone in our quest to address real-world clinical challenges, combat HIV drug resistance and meet the diverse needs of those living with HIV,” said Brian Woodfall, M.D., Global Head of Late Development, Infectious Diseases, Janssen Pharmaceutica NV. “There is more to be done in our fight to make HIV history, and we will not stop here. We will continue our efforts to advance treatment and remain steadfast in our pursuit of fulfilling the dream of a preventive HIV vaccine.”

The recommended dosage of SYMTUZA™ is one tablet taken once-daily with food. SYMTUZA™ is not recommended in patients with creatinine clearance below 30 mL per minute or those with severe hepatic impairment.

According to the Prescribing Information, prior to or when initiating treatment with SYMTUZA™, patients should be tested for hepatitis B virus (HBV) infection and renal function, and renal function should be monitored as clinically appropriate during therapy. See below for Important Safety Information.

SYM TUZA™ has also been [approved by the European Commission](#) (EC) and Health Canada for the treatment of HIV-1 infection in adults and adolescents aged 12 years and older with body weight of at least 40 kg. European approval allows Janssen to market SYMTUZA™ in all member states of the European Union and the European Economic Area. Janssen plans additional regulatory filings in other markets worldwide, and additional SYMTUZA™ data, including data from an ongoing Phase 3 rapid initiation study (DIAMOND) will be presented at AIDS 2018 in Amsterdam, The Netherlands in late July.

Cobicistat, emtricitabine and tenofovir alafenamide are from Gilead Sciences, Inc.

Full Prescribing Information is available [here](#). To learn more about Janssen's commitment to the prevention and treatment of HIV, please visit jnj.com/HIV.

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Notes to editors

Cobicistat, emtricitabine and TAF are from Gilead Sciences, Inc. On December 23, 2014, Janssen and Gilead Sciences Inc. amended a licensing agreement for the development and commercialization of a once-daily, darunavir-based STR including Gilead's TAF, emtricitabine and cobicistat. Under the terms of the agreement, Janssen and its affiliates are responsible for the manufacturing, registration, distribution and commercialization of SYMTUZA™ worldwide.

WHAT IS SYMTUZA™?

SYM TUZA™ is a prescription medicine that is used without other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults who:

- have not received anti-HIV-1 medicines in the past, **or**
- when their healthcare provider determines that they meet certain requirements.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about SYMTUZA™?

SYM TUZA™ can cause serious side effects including:

- **Worsening of hepatitis B virus infection.** Your healthcare provider will test you for hepatitis B virus (HBV) before starting treatment with SYMTUZA™. If you have HBV infection and take SYMTUZA™, your HBV may get worse (flare-up) if you stop taking SYMTUZA™.

- Do not stop taking SYMTUZA™ without first talking to your healthcare provider.
- Do not run out of SYMTUZA™. Refill your prescription or talk to your healthcare provider before your SYMTUZA™ is all gone.
- If you stop taking SYMTUZA™, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection or give you a medicine to treat your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking SYMTUZA™.
- **Change in liver enzymes.** People with a history of hepatitis B or C virus infection or who have certain liver enzyme changes may have an increased risk of developing new or worsening liver problems during treatment with SYMTUZA™. Liver problems can also happen during treatment with SYMTUZA™ in people without a history of liver disease. Your healthcare provider may need to do tests to check your liver enzymes before and during treatment with SYMTUZA™.
- **Severe liver problems.** In rare cases, severe liver problems can happen that can lead to death. **Tell your healthcare provider right away if you get these symptoms:**
 - Skin or the white part of your eyes turn yellow
 - Dark “tea-colored” urine
 - Light-colored stools
 - Loss of appetite for several days or longer
 - Nausea
 - Vomiting
 - Stomach area pain

SYMTUZA™ may cause severe or life-threatening skin reactions or rashes which may sometime require treatment in a hospital. Call your healthcare provider right away if you develop a rash. **Stop taking SYMTUZA™** and call your healthcare provider right away if you develop any skin changes with symptoms below:

- Fever
- Tiredness
- Muscle or joint pain
- Blisters or skin lesions
- Mouth sores or ulcers
- Red or inflamed eyes, like “pink eye” (conjunctivitis)

Who should not take SYMTUZA™?

- Do not take SYMTUZA™ with any of the following medicines: alfuzosin, carbamazepine, cisapride, colchicine (if you have liver or kidney problems), dronedarone, elbasvir and grazoprevir, ergot-containing medicines (such as: dihydroergotamine, ergotamine tartrate, methylergonovine), lovastatin or a product that contains lovastatin, lurasidone, oral midazolam (when taken by mouth), phenobarbital, phenytoin, pimozone, ranolazine, rifampin, St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort, sildenafil when used for pulmonary arterial hypertension (PAH), simvastatin or a product that contains simvastatin, or triazolam.
- Serious problems can happen if you take any of these medicines with SYMTUZA™.

Before taking SYMTUZA™, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems (including hepatitis B or hepatitis C), have kidney problems, are allergic to sulfa (sulfonamide), have diabetes, have hemophilia, or have any other medical condition.
- are pregnant (if you become pregnant while taking SYMTUZA™), or plan to become pregnant. It is unknown if SYMTUZA™ will harm your unborn baby.
 - SYMTUZA™ should not be used during pregnancy.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take SYMTUZA™.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with SYMTUZA™. Keep a list of your medicines to show your healthcare provider and pharmacist. **Do not start taking a new medicine without telling your healthcare provider.**

How should I take SYMTUZA™?

- Take SYMTUZA™ 1 time a day with food.

What are the possible side effects of SYMTUZA™?

SYMTUZA™ may cause serious side effects including:

- See **"What is the most important information I should know about SYMTUZA™?"**
- **Immune system changes** can happen in people who start HIV medications.
- **New or worse kidney problems, including kidney failure.**
 - Your healthcare provider should do blood and urine tests to check your kidneys before you start and while you are taking SYMTUZA™.
- **Too much lactic acid in your blood (lactic acidosis).**
 - Too much lactic acid is a serious but rare medical emergency that can lead to death. **Tell your healthcare provider right away if you get these symptoms:** weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.
- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including SYMTUZA™ can get high blood sugar, develop diabetes, or your diabetes can get worse. Tell your healthcare provider if you notice an increase in thirst or if you start urinating more often while taking SYMTUZA™.
- **Changes in body fat** can happen in people taking HIV-1 medications.
- **Increased bleeding** can occur in people with hemophilia who are taking SYMTUZA™.

The most common side effects of SYMTUZA™ are: Diarrhea, rash, nausea, fatigue, headache, stomach problems, and gas.

These are not all of the possible side effects of SYMTUZA™.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit

<http://www.fda.gov/medwatch> or call 1-800-FDA-1088. You may also report side effects to Janssen Products, LP at 1-800-JANSSEN (1-800-526-7736).

Please see full [Product Information](#), including **Boxed Warning for SYMTUZA™.**

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. Follow us at www.twitter.com/JanssenUS and www.twitter.com/JanssenGlobal.

Janssen Therapeutics, Division of Janssen Products, LP will market SYMTUZA™ in the United States. Both Janssen Products, LP and Janssen Pharmaceutica NV are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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 and benefits of new treatment options of SYMTUZA™ 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 Therapeutics, Division of Janssen Products, LP, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; 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 behavior 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 descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements," and "Item 1A." Risk Factors, and in the company's subsequent Quarterly Reports on Form 10-Q and other 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. Neither the Janssen

Pharmaceutical Companies nor 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. <https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf>