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Janssen Presents New Data from First Phase 3 Trial of a Single-Tablet Regimen in a Rapid Initiation Model of Care Demonstrating Safety and Efficacy with SYMTUZA® through 48 Weeks

High Proportion of Patients Achieve Undetectable Viral Loads after Rapidly Starting SYMTUZA®[1]

MIAMI, FLA., APRIL 11, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson unveiled new 48-week data for SYMTUZA® (darunavir 800 mg, cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide 10 mg D/C/F/TAF) showing that a high proportion of HIV patients achieved an undetectable viral load through 48 weeks after rapidly starting SYMTUZA®. A secondary endpoint of the study also showed that 97% of patients reported they were satisfied with their treatment.[1] The results from the DIAMOND study – the first prospective Phase 3 trial studying the rapid initiation of a single-tablet regimen (STR) – were presented at the 13th Annual American Conference for the Treatment of HIV (ACTHIV 2019) in Miami, Florida.

The DIAMOND study evaluated the once-daily STR SYMTUZA® for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult patients who were enrolled within 14 days of receiving an HIV diagnosis and then started on SYMTUZA® before laboratory or baseline resistance test results were available.[1] SYMTUZA® is approved by the U.S. Food & Drug Administration (FDA) for the treatment of HIV-1 infection in treatment-naïve and certain virologically suppressed adults.

***Click to Tweet**: Janssen announces new #HIV data for patients rapidly starting treatment at #ACTHIV2019. Read full press release here: http://po.st/LK3iIr*

Click to Tweet: *@JanssenUS announces exciting new data for SYMTUZA® that is being presented at a conference in Miami. Learn more: http://po.st/LK3iIr. Click here for full Prescribing Information for SYMTUZA®, including Boxed WARNING: http://po.st/Tix2oN*

"Rapid initiation of antiretroviral treatment is becoming the recognized standard of care for newly diagnosed HIV-1 patients, as it has the potential to improve treatment outcomes, including the probability of a person adhering to treatment and staying in care, and could be an additional strategy in our quest to achieve the 90/90/90 prevention and treatment goals as outlined by UNAIDS," said Moti Ramgopal, M.D., Infectious Disease Director, Midway Immunology and Research Center, Fort Pierce, Florida.* "The DIAMOND study is the first evidence-based STR-specific trial in a rapid initiation model of care. SYMTUZA® was well-tolerated, and a high proportion of patients achieved undetectable viral loads of less than 50 c/mL after 48 weeks."

DIAMOND is a Phase 3, single-arm, open-label, prospective, multicenter 48-week study evaluating the efficacy and safety of rapidly initiating SYMTUZA®.[1] These 48-week data, which follow on from the interim 24-week results presented at the 2018 International AIDS Conference (AIDS 2018), confirm the safety, efficacy and tolerability profile of rapidly starting SYMTUZA® as a treatment for antiretroviral treatment (ART)-naïve adults with HIV-1.[1]

Through 48 weeks, almost 90% (97/109) of patients enrolled in DIAMOND completed the study.[1] In the primary intent-to-treat (ITT) analysis, 84% (92/109) of patients achieved undetectable viral loads (viral load <50 c/mL; FDA-snapshot), and 8% (9/109) of patients had virologic failure (viral load ≥50 c/mL; FDA-snapshot) at 48 weeks.[1]

Additionally, in an observed analysis – which excluded those with missing data – 96% (92/96) of patients achieved undetectable viral loads, and 100% (96/96) of patients achieved viral loads of <200 c/mL at Week 48, with no patients discontinuing treatment with SYMTUZA® due to lack of efficacy.[1]

SYMTUZA® was well-tolerated with no serious related adverse events (AEs). Most AEs were grade 1 or 2 in severity, and only two patients experienced a grade 3 drug-related AE, with one patient discontinuing the trial due to adverse events.[1] The most common adverse drug reactions related to SYMTUZA® (all grades, ≥2% of adults) were diarrhea, nausea, rash, vomiting and fatigue.[1] Grade 3 and 4 laboratory abnormalities, occurring in ≥2% of patients, included increases in aspartate aminotransferase (5%), alanine aminotransferase (3%) or bilirubin (3%).[1]

Prior to or when initiating SYMTUZA®, patients should undergo testing for hepatitis B virus (HBV) and renal function. Appropriate laboratory tests, including liver testing, hepatitis serology and HIV genotypic resistance testing, should be conducted, and patients should be monitored during treatment as clinically appropriate.[1]

As another key endpoint, the DIAMOND study also collected the first-known patient-reported outcomes in a Phase 3 rapid initiation trial via a validated HIV Treatment Satisfaction Questionnaire. On a 60-point scale, patients in the DIAMOND trial consistently reported high satisfaction scores (average scores ranging from 56 to 58) regarding treatment with SYMTUZA®.[1] When asked specifically about their current treatment (SYMTUZA®), 97% of patients reported they were satisfied with their treatment.[1]

"When you're first diagnosed with HIV, your entire world changes, and there are so many questions and uncertainties. However, one thing I did know was that getting on treatment as soon as possible was the most important thing for me to do so I could keep living," said Brandon B., DIAMOND clinical trial patient. "As a participant in the DIAMOND trial, I was grateful for the opportunity to make treatment part of my daily routine with SYMTUZA®."

Darunavir has been studied in more than 5,500 patients in 14 clinical trials with data up to 192 weeks.[2,3] The U.S. Department of Health and Human Services (DHHS) guidelines recommend darunavir-based regimens, such as SYMTUZA®, for patients who may require the rapid initiation of ART before full blood work is available.[4] The International Antiviral Society (IAS)-USA guidelines also recommend darunavir-based regimens for rapidly initiating treatment.[5] Additionally, the DHHS guidelines recommend darunavir-based regimens for those who may have suboptimal adherence and face the risk of developing HIV drug resistance, which is when a medication stops working to fight the virus.[4]

Several studies examining rapid initiation in newly diagnosed adults with HIV-1 have previously underscored the benefits of linking people with HIV to treatment services soon after diagnosis, including improved virologic outcomes, retention in care and decreased morbidity/mortality.[6,7,8] While achieving viral suppression is always a main goal of treatment for individuals, these studies have also found that rapid initiation may get patients to undetectable viral loads more quickly and sustain them over time.

"At Janssen, we're committed to the research and development of medicines and solutions that have the potential to change the treatment paradigm for people living with HIV – across the care continuum," said Richard Nettles, M.D., Vice President, Medical Affairs, Janssen Infectious Diseases, Janssen Scientific Affairs, LLC. "The DIAMOND study mirrors real clinical scenarios that physicians face today – including the need to start treatment before lab or baseline resistance test results are available – and highlights the benefits this model of care can bring to those newly diagnosed with HIV. SYMTUZA® is the only single-tablet regimen proven in a Phase 3 clinical trial studying the rapid initiation of treatment, further demonstrating it as a treatment option for people new to HIV therapy."

SYMTUZA® was approved by the U.S. Food & Drug Administration (FDA) in July 2018 for treatment-naïve and certain virologically suppressed adults. The approval was based on the results from the two pivotal Phase 3 studies, EMERALD and AMBER.[9,10] Ninety-six-week results from the Phase 3 EMERALD and AMBER trials were presented at IDWeek and the HIV Glasgow Congress, respectively, in Fall 2018.[11,12]

SYMTUZA® 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.

SYMTUZA® does not cure or prevent HIV-1 or AIDS.

Please see Important Safety Information below, including Boxed Warning for SYMTUZA®.

To learn more about Janssen's commitment to the prevention and treatment of HIV, please visit jnj.com/HIV.

**Dr. Ramgopal has received research support from Janssen and has served as a paid consultant to the company.*

About DIAMOND[1]

DIAMOND is a Phase 3, single-arm, open-label, prospective, multicenter, 48-week study assessing the efficacy/safety of rapidly initiating SYMTUZA® 800/150/200/10 mg. Adults

diagnosed with HIV-1 infection within 14 days were enrolled and started on SYMTUZA® without screening/baseline laboratory or HIV genotypic resistance information available. Investigators reviewed screening/baseline laboratory and resistance findings as results became available; patients not meeting predefined safety or resistance stopping rules continued treatment.

Resistance was evaluated based on predicted genotypic sensitivity (there was no exclusion based on the presence of specific resistance-associated mutations). Patients who did not show full genotypic sensitivity to the components of SYMTUZA® (assessed using GenoSure PRIme®) would be required to stop the study; an exception was resistance to lamivudine/emtricitabine associated with the M184I or V mutation alone.

Screening/baseline safety laboratory findings were evaluated on Day 3 (±1 week), with the following stopping criteria:

- eGFR (MDRD formula) <50 mL/min
- Aspartate aminotransferase or alanine aminotransferase ≥2.5 times the upper limit of normal (ULN)
- Serum lipase ≥1.5 times the ULN
- Positive pregnancy test for women of childbearing potential
- Laboratory results that the investigator believes should result in discontinuation of study medication
- Active hepatitis C infection that required immediate treatment or is expected to require treatment during the study with agents not compatible with SYMTUZA®

For more information on this clinical trial, please visit: **www.clinicaltrials.gov**

WHAT IS SYMTUZA®?

SYMTUZA® 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®?

SYMTUZA® 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 sometimes 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), lomitapide, lovastatin or a product that contains lovastatin, lurasidone, oral midazolam (when taken by mouth), phenobarbital, phenytoin, pimozide, 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®.

Notes to editors

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 commercialization 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 commercialization of this single-tablet regimen worldwide.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal. Janssen Scientific Affairs, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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