News Release

Media contacts:
Lisa Vaga
Office: (609) 730-2020
Mobile: (908) 670-0363

Ronan Collins
Mobile: +47 488 425 00

Investor contacts:
Lesley Fishman
Phone: (732) 524-3922

Louise Mehrotra
Phone: (732) 524-6491

PREZCOBIX™ (darunavir/cobicistat) Approved in the U.S. for the Treatment of Adults Living With HIV-1

Combined Fixed-Dose Tablet of Darunavir and Cobicistat Can Help Reduce Number of Pills in a Combination Antiretroviral Treatment Regimen

TITUSVILLE, NJ, January 29, 2015 – Janssen Therapeutics, Division of Janssen Products, LP (Janssen), today announced the U.S. Food and Drug Administration (FDA) has approved PREZCOBIX™ (darunavir 800 mg/cobicistat 150 mg) tablets, an HIV-1 protease inhibitor combined with a CYP3A4 inhibitor, for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral agents for treatment-naïve and treatment-experienced adults with no darunavir resistance-associated substitutions.[1]

PREZCOBIX™ is a once-daily, fixed-dose antiretroviral combination tablet containing 800 mg of darunavir, marketed as PREZISTA® in the United States, and 150 mg of cobicistat, a pharmacokinetic enhancer or "boosting" agent, developed and marketed as Tybost® by Gilead Sciences, Inc., taken orally with other HIV-1 medications and with food.

“Additional options remain an important medical priority to meet the diverse needs of those living with and managing this disease,” said Karen Tashima, M.D., professor of medicine in the Division of Infectious Diseases, Brown University, director of HIV Clinical Studies, Miriam Hospital, and a lead investigator in the GS-US-216-0130 study. “This approval gives physicians the option of a darunavir-based fixed-dose combination tablet to treat adults living with the HIV-1 infection, which can help reduce the number of pills in their overall treatment regimen.”

The FDA approval was based on bioequivalence data evaluating the use of a darunavir and cobicistat fixed-dose combination tablet versus single agents (TMC114IFD1003) and a clinical study evaluating the safety and efficacy of cobicistat-boosted darunavir for the treatment of HIV-1 in adults with no darunavir resistance-associated mutations (GS-US-216-0130).

The efficacy of PREZCOBIX™ is based on efficacy demonstrated in clinical trials of darunavir co-administered with ritonavir and pharmacokinetic trials showing similar exposures of darunavir when boosted with cobicistat compared to darunavir boosted with ritonavir. Two Phase 3 studies in the darunavir clinical development program, ARTEMIS (TMC114-C211) and ODIN (TMC114-C229), studied the once-daily use of darunavir co-administered with ritonavir.

In the GS-US-216-0130 study, which was conducted with darunavir 800 mg and cobicistat 150 mg administered as single entities in 313 HIV-infected patients, adverse reactions evaluated through Week 24 did not differ substantially from those reported in clinical trials with darunavir co-administered with ritonavir 100 mg. During the darunavir clinical development program, where darunavir was co-administered with ritonavir 100 mg once or twice daily, the most common adverse reactions (incidence greater than or equal to 5 percent) of at least moderate intensity (greater than or equal to Grade 2) were diarrhea, nausea, rash, headache, abdominal pain and vomiting.[1]

HIV was first reported in 1981[2] and remains a challenging disease and public health concern worldwide. In the United States today, an estimated 1.2 million people live with HIV[3] and the number of Americans being diagnosed with HIV every year – about 50,000 – has not declined since the mid-1990s.[4]

“Treating HIV remains an urgent healthcare need, and it’s important for adults living with HIV to have regular discussions with a healthcare provider about treatment options that are right for them,” said Richard Nettles, M.D., vice president of Medical Affairs, Janssen Therapeutics. “The

approval of PREZCOBIX™ exemplifies Janssen's ongoing commitment to developing new treatment options for those living with HIV and builds upon the legacy of darunavir."

Access to PREZCOBIX™

Janssen partners with a variety of stakeholders to support patient access to medicines. For patients, the company offers Janssen Therapeutics Line, a comprehensive support offering designed to help patients start on their therapy with Janssen HIV products. Janssen Therapeutics Line provides benefit verification, assistance with the prior authorization process and information about a variety of affordability programs, including those for patients with commercial insurance, federally funded insurance or no insurance coverage.

Eligible patients with commercial insurance coverage for PREZCOBIX™ may pay $0 each time they fill their prescription with the Janssen Therapeutics Patient Savings Program. This is subject to a $7,500 maximum benefit per calendar year. This program is not valid for patients covered under Medicaid, Medicare or similar state or federal programs. For more information, visit www.PREZCOBIX.com or call 1-866-836-0114, 8:00 a.m. - 8:00 p.m. (EST), Monday through Friday.

About PREZCOBIX™

PREZCOBIX™ (darunavir/cobicistat) tablets is a prescription medicine indicated for the treatment of human immunodeficiency virus (HIV-1) in combination with other antiretroviral agents for treatment-naive and treatment-experienced adult patients with no darunavir resistance-associated substitutions (V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V, L89V). It combines the protease inhibitor darunavir (marketed as PREZISTA® in the United States) with cobicistat, a pharmacokinetic enhancer or boosting agent, developed by Gilead Sciences, Inc., and marketed as Tybost®, for use in combination with other HIV-1 medications taken orally with food.

For additional information about PREZCOBIX™, please visit www.PREZCOBIX.com.

WHAT IS PREZCOBIX™?

- PREZCOBIX™ is a prescription HIV-1 (Human Immunodeficiency Virus 1) medicine used with other antiretroviral medicines to treat HIV-1 infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). PREZCOBIX™ contains the prescription medicines PREZISTA® (darunavir) and TYBOST® (cobicistat).
- It is not known if PREZCOBIX™ is safe and effective in children under 18 years of age.

- **When used with other antiretroviral medicines to treat HIV-1 infection, PREZCOBIX™ may help:**
    - reduce the amount of HIV-1 in your blood. This is called "viral load."
    - increase the number of CD4+ (T) cells in your blood that help fight off other infections.
- PREZCOBIX™ is always taken in combination with other HIV medications for the treatment of HIV-1 infection in adults. PREZCOBIX™ should be taken once daily with food.
- PREZCOBIX™ does not cure HIV-1 infection or AIDS, and you may still experience illnesses associated with HIV-1 infection. You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.
- Ask your healthcare provider if you have any questions on how to prevent passing HIV to other people.
- **Please read the Important Safety Information below and talk to your healthcare provider to learn if PREZCOBIX™ is right for you.**

IMPORTANT SAFETY INFORMATION

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

- **PREZCOBIX™ may cause liver problems.** Some people taking PREZCOBIX™ may develop liver problems which may be life-threatening. Your healthcare provider should do blood tests before and during your treatment with PREZCOBIX™.
    - Chronic hepatitis B or C infection may increase your chance of developing liver problems. Your healthcare provider should check your blood tests more often.
    - Signs and symptoms of liver problems include dark (tea-colored) urine, yellowing of your skin or whites of your eyes, pale-colored stools (bowel movements), nausea, vomiting, pain or tenderness on your right side below your ribs, or loss of appetite. Tell your healthcare provider if you develop any of these symptoms.

- **PREZCOBIX™ may cause severe or life-threatening skin reactions or rash.** Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. Call your healthcare provider right away if you develop a rash.
    - **Stop taking PREZCOBIX™** and call your healthcare provider right away if you develop any skin changes with symptoms such as fever, tiredness, muscle or joint pain, blisters or skin lesions, mouth sores or ulcers, red or inflamed eyes like "pink eye" (conjunctivitis).

- **PREZCOBIX™, when taken with certain other medicines, can cause new or worse kidney problems, including kidney failure**. Your healthcare provider should check your kidneys before you start and while you are taking PREZCOBIX™.

Who should not take PREZCOBIX™?

- **Do not take PREZCOBIX™** with any of the following medicines: alfuzosin (Uroxatral®), cisapride (Propulsid®, Propulsid® Quicksolv), colchicine (Colcrys®, Mitigare®, if you have liver or kidney problems), dronedarone (Multaq®), dihydroergotamine (D.H.E.45®, Embolex®,

Migranal®), ergotamine tartrate (Cafergot®, Ergomar®, Ergostat®, Medihaler®, Migergot®, Wigraine®, Wigrettes®), methylergonovine (Methergine®), lovastatin or a product that contains lovastatin (Altoprev®, Advicor®, Mevacor®), lurasidone (Latuda®), oral midazolam (Versed®), pimozide (Orap®), ranolazine (Ranexa®), rifampin (Rifadin®, Rifater®, Rifamate®, Rimactane®), sildenafil (Revatio®) when used for pulmonary arterial hypertension (PAH), simvastatin or a product that contains simvastatin (Simcor®, Vytorin®, Zocor®), St. John's Wort (*Hypericum perforatum)* or a product that contains St. John's Wort, or triazolam (Halcion®).

- Serious problems can happen if you take any of these medicines with PREZCOBIX™.

What should I tell my healthcare provider before taking PREZCOBIX™?

- **About all health problems.** Tell your healthcare provider 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, breastfeeding, or plan to become pregnant or breastfeed. Tell your healthcare provider if you become pregnant while taking PREZCOBIX™.
- **About all medicines you take.** 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 PREZCOBIX™. **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.** Your healthcare provider can tell you if it is safe to take PREZCOBIX™ with other medicines.

What are the possible side effects of PREZCOBIX™?

- **The most common side effects of darunavir, one of the medicines in PREZCOBIX™, include** diarrhea, nausea, rash, headache, stomach area (abdominal) pain, and vomiting.

- **Other possible side effects include:**
    - **High blood sugar, diabetes or worsening diabetes, and increased bleeding in people with hemophilia** have been reported in patients taking protease inhibitor medicines, including PREZCOBIX™.
    - **Changes in body fat can happen in people who take HIV-1 medicines.** The exact cause and long-term health effects of these changes are not known.
    - **Changes in your immune system** (Immune Reconstitution Syndrome) can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time.

These are not all of the possible side effects of PREZCOBIX™. For more information, ask your healthcare provider.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Product Information for more details.

About Janssen Therapeutics

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in HIV, hepatitis C and other infectious diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Headquartered in Titusville, New Jersey, Janssen Therapeutics, Division of Janssen Products, LP, is one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Visit www.JanssenTherapeutics.com for more information and follow us on Twitter at @JanssenUS.

For full product information for darunavir, visit www.PREZISTA.com.

Cobicistat is marketed by Gilead Sciences, Inc., as Tybost®.

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[1] PREZCOBIX™ (darunavir and cobicistat). Prescribing Information. United States. Janssen Therapeutics. January 2015.
[2] Centers for Disease Control and Prevention. *MMWR.* 2001;50(21);429-456.
[3] Centers for Disease Control and Prevention. "Today's HIV/AIDS Epidemic." 2013. http://www.cdc.gov/nchhstp/newsroom/docs/hivfactsheets/todaysepidemic-508.pdf. Accessed January 2015.
[4] Centers for Disease Control and Prevention. HIV/AIDS Surveillance Report. 2012; vol 24. http://www.cdc.gov/hiv/pdf/statistics_2012_HIV_Surveillance_Report_vol_24.pdf. Accessed January 2015.