Janssen Announces Collaboration with Gilead to Develop Prezista®-Based Single-Tablet Regimen for the Treatment of People Living with HIV

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Cork, Ireland, 29 December 2014 - Janssen R&D Ireland (Janssen) announced today an amendment to its existing agreement with Gilead Sciences, Inc. (Gilead), initially established in 2011, for the development of a once daily, darunavir-based, single-tablet regimen (STR) for the treatment of people living with HIV. This new STR contains a combination of darunavir (PREZISTA®), cobicistat (TYBOST®), emtricitabine and tenofovir alafenamide (TAF). A number of Phase 1 and 2 studies of the new STR have been completed. Under this amended agreement, Janssen will conduct all further clinical development of the regimen and, subject to regulatory approval, will be responsible for all manufacturing, registration, distribution and commercialization of the product worldwide.

If successfully developed and approved by regulatory authorities, this treatment would represent the first protease inhibitor-based STR and thereby continue Janssen's commitment to providing its HIV products in more simplified dosing presentations.

"Janssen has vast experience in developing and making innovative HIV treatments available to patients and we have engaged in several successful collaborations with Gilead. We are proud to be extending our collaboration and leading the development of this darunavir-based single-tablet regimen," says Paul Stoffels, Chief Scientific Officer and Worldwide Chairman, Pharmaceuticals, Johnson & Johnson. "Our ultimate goal is to offer new treatment options for people living with HIV. If approved, this STR has the potential to provide additional choice in the form of another one pill, once a day, as a new and simplified regimen."

In addition to this collaboration, Janssen and Gilead have also expanded a separate agreement initiated in 2009 regarding the approved single-tablet regimen, COMPLERA®, marketed as EVIPLERA® in the European Union (EU) (rilpivirine, tenofovir disoproxil fumarate (TDF) and emtricitabine). This expanded agreement will allow for Gilead's investigational tenofovir alafenamide (TAF), a novel nucleotide reverse transcriptase inhibitor, to replace TDF within COMPLERA®/ EVIPLERA®. TAF has been shown in clinical trials to have a better renal and bone safety profile than TDF.[1] Gilead will be responsible for the development and commercialization in most countries, while Janssen will lead the commercialization in select markets.

Since the beginning of the HIV epidemic, almost 75 million people have been infected with the HIV virus.[2] It is estimated that 35 million people are currently living with HIV globally, with 2.5 million people becoming newly infected each year.[2,3,4]

PREZISTA®
Indication
PREZISTA® (darunavir), coadministered with ritonavir (PREZISTA®/r), and with other antiretroviral agents (ARVs), is indicated for the treatment of human immunodeficiency virus (HIV-1) infection.

This indication is based on analyses of plasma HIV-1 RNA levels and CD4+ cell counts from 2 controlled Phase 3 trials of 48 weeks duration in ARV treatment-naïve and treatment-experienced patients and 2 controlled Phase 2 trials of 96 weeks duration in clinically advanced, treatment-experienced adult patients.

In treatment-experienced adult patients, the following points should be considered when initiating therapy with PREZISTA®/r:

- Treatment history and, when available, genotypic or phenotypic testing should guide the use of PREZISTA®/r
- The use of other active agents with PREZISTA®/r is associated with a greater likelihood of treatment response

Important Safety Information

PREZISTA® (darunavir) is a prescription medicine. It is one treatment option in the class of HIV (human immunodeficiency virus) medicines known as protease inhibitors.

PREZISTA® is always taken with and at the same time as ritonavir (Norvir®), in combination with other HIV medicines for the treatment of HIV infection in adults. PREZISTA® should also be taken with food.

- The use of other medicines active against HIV in combination with PREZISTA®/ritonavir (Norvir®) may increase your ability to fight HIV. Your healthcare professional will work with you to find the right combination of HIV medicines
- It is important that you remain under the care of your healthcare professional during treatment with PREZISTA®

PREZISTA® does not cure HIV infection or AIDS and you may continue to experience illnesses associated with HIV-1 infection, including opportunistic infections. You should remain under the care of a doctor when using PREZISTA®.
Please read Important Safety Information below, and talk to your healthcare professional to learn if PREZISTA® is right for you.
Important Safety Information
What is the most important information I should know about PREZISTA®?

- **PREZISTA® can interact with other medicines and cause serious side effects. See "Who should not take PREZISTA®?"**

- **PREZISTA® may cause liver problems.** Some people taking PREZISTA®, together with Norvir® (ritonavir), have developed liver problems which may be life-threatening. Your healthcare professional should do blood tests before and during your combination treatment with PREZISTA®. If you have chronic hepatitis B or C infection, your healthcare professional should check your blood tests more often because you have an increased chance of developing liver problems
- Tell your healthcare professional if you have any of these signs and symptoms of liver problems: 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
- **PREZISTA® may cause a severe or life-threatening skin reaction or rash.** Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. You should call your healthcare professional immediately if you develop a rash. However, stop taking PREZISTA® and ritonavir combination treatment and call your healthcare professional immediately if you develop any skin changes with these symptoms: fever, tiredness, muscle or joint pain, blisters or skin lesions, mouth sores or ulcers, red or inflamed eyes, like "pink eye." Rash occurred more often in patients taking PREZISTA® and raltegravir together than with either drug separately, but was generally mild

Who should not take PREZISTA®?

- **Do not take PREZISTA® if you are taking the following medicines:** alfuzosin (Uroxatral®), dihydroergotamine (D.H.E.45®, Embolex®, Migranal®), ergonovine, ergotamine (Cafergot®, Ergomar®), methylergonovine, cisapride (Propulsid®), pimozide (Orap®), oral midazolam, triazolam (Halcion®), the herbal supplement St. John's wort (Hypericum perforatum), lovastatin (Mevacor®, Altoprev®, Advicor®), simvastatin (Zocor®, Simcor®, Vytorin®), rifampin (Rifadin®, Rifater®, Rifamate®, Rimactane®), sildenafil (Revatio®) when used to treat pulmonary arterial hypertension, indinavir (Crixivan®), lopinavir/ritonavir (Kaletra®), saquinavir (Invirase®), boceprevir (Victrelis™), or telaprevir (Incivek™)
- Before taking PREZISTA®, tell your healthcare professional if you are taking sildenafil (Viagra®, Revatio®), vardenafil (Levitra®, Staxyn®), tadalafil (Cialis®, Adcirca®), atorvastatin (Lipitor®), rosuvastatin (Crestor®), pravastatin (Pravachol®), or colchicine (Colcrys®, Col-Probenecid®). Tell your healthcare professional if you are taking estrogen-based contraceptives (birth control). PREZISTA® might reduce the effectiveness of estrogen-based contraceptives. You must take additional precautions for birth control, such as condoms

This is not a complete list of medicines. Be sure to tell your healthcare professional about all the medicines you are taking or plan to take, including prescription and nonprescription medicines, vitamins, and herbal supplements.
What should I tell my doctor before I take PREZISTA®?

- Before taking PREZISTA®, tell your healthcare professional if you have any medical conditions, including liver problems (including hepatitis B or C), allergy to sulfa medicines, diabetes, or hemophilia
- Tell your healthcare professional if you are pregnant or planning to become pregnant, or are breastfeeding
    - The effects of PREZISTA® on pregnant women or their unborn babies are not known. You and your healthcare professional will need to decide if taking PREZISTA® is right for you
    - **Do not breastfeed.** It is not known if PREZISTA® can be passed to your baby in your breast milk and whether it could harm your baby. Also, mothers with HIV should not breastfeed because HIV can be passed to your baby in the breast milk

What are the possible side effects of PREZISTA®?

- High blood sugar, diabetes or worsening of diabetes, and increased bleeding in people with hemophilia have been reported in patients taking protease inhibitor medicines, including PREZISTA®
- Changes in body fat have been seen in some patients taking HIV medicines, including PREZISTA®. The cause and long-term health effects of these conditions are not known at this time
- Changes in your immune system can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden
- The most common side effects related to taking PREZISTA® include diarrhea, nausea, rash, headache, stomach pain, and vomiting. This is not a complete list of all possible side effects. If you experience these or other side effects, talk to your healthcare professional. Do not stop taking PREZISTA® or any other medicines without first talking to your healthcare professional

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 refer to the ritonavir (Norvir®) Product Information (PI and PPI) for additional information on precautionary measures.

Please see full Product Information for more details:
http://www.prezista.com/sites/default/files/pdf/us_package_insert.pdf#zoom=100

About Janssen Pharmaceutical Companies of Johnson & Johnson
The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving some of the most important unmet medical

needs of our time in infectious diseases and vaccines, oncology, immunology, neuroscience, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world.

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 including regarding product development. 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 R&D Ireland and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; changes to regulations and domestic and foreign health care reforms; and general industry conditions, including 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 fiscal year ended December 29, 2013, including in Exhibit 99 thereto, 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 undertake to update any forward-looking statement as a result of new information or future events or developments.

[1]Sax P, Brar I, Elion R, et al. 48 Week study of tenofovir alafenamide (TAF) versus tenofovir disoproxil fumarate (TDF), each in a single tablet regimen with elvitegravir, cobicistat, and emtricitabine for initial HIV treatment. 53rd ICAAC. September 10-13, 2013. Denver. Abstract H1464d.

[2] World Health Organization. Global summary of the AIDS epidemic. Available at: http://www.who.int/gho/hiv/en/. Last accessed July 2014.

[3] Hui Dy. Effects of HIV protease inhibitor therapy on lipid metabolism. *Prog Lipid Res* 2003; 42(2):81-92.

[4] World Health Organization. Global summary of the AIDS epidemic. Available at: http://www.who.int/hiv/data/2012_epi_core_en.png . Last accessed July 2014.

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