Janssen Collaborates With ViiV Healthcare To Develop Two-Drug Single Tablet Regimen For The Maintenance Treatment Of People Living With HIV

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Cork, Ireland, 12 June 2014 - Janssen R&D Ireland Ltd announced today that they have entered into a collaboration with ViiV Healthcare to develop and commercialize a new single tablet regimen containing Janssen's Non-Nucleoside Reverse Transcriptase Inhibitor rilpivirine (marketed as EDURANT®) and ViiV's Integrase Inhibitor dolutegravir (marketed as TIVICAY®) as the sole active ingredients for the maintenance treatment of people living with Human Immunodeficiency Virus (HIV). The companies will further investigate development of this drug combination for paediatric use.

If successfully developed and approved by regulatory authorities, this treatment could offer people living with HIV who are virologically suppressed an option to switch from a standard three-drug therapy to a two-drug, Nucleoside Reverse Transcriptase Inhibitor (NRTI)-sparing antiviral regimen.

"HIV remains a significant medical challenge, and our goal is to find new treatment regimens for patients," says Paul Stoffels, Chief Scientific Officer, Johnson & Johnson and Worldwide Chairman, Janssen. "We are pleased to collaborate with ViiV Healthcare in pursuing this shift in the HIV treatment paradigm and reaffirm our commitment to collaborate and develop new HIV treatments and fixed-dose regimens."

Formulation and clinical development for the single tablet regimen will begin in the coming months.

Since the beginning of the HIV epidemic, almost 75 million people have been infected with the HIV virus.[1] It is estimated that 35 million people are currently living with HIV globally, with 2.5 million people becoming newly infected each year.[1, 2, 3]
Standard HIV-drug therapy contains three active components: a backbone of two NRTIs, plus either a Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI), Protease Inhibitor (PI) or Integrase Inhibitor (INI).

EDURANT®

- EDURANT® (rilpivirine) is a prescription HIV medicine that is used with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1)
  - in adults:
  - Who have **never** taken HIV medicines before, **and**
  - Who have an amount of HIV in their blood (called "viral load") that is no more than 100,000 copies/mL. Your healthcare professional will measure your viral load
- EDURANT® should be taken in combination with other HIV medicines. 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 EDURANT®
- EDURANT® is not recommended for patients less than 18 years of age

EDURANT® does not cure HIV infection or AIDS. You should remain on your HIV medications without stopping to ensure that you control your HIV infection and decrease the risk of HIV-related illnesses. Ask your healthcare professional about how to prevent passing HIV to other people.

Please read Important Safety Information below, and talk to your healthcare professional to learn if EDURANT® is right for you.

Important Safety Information
Can EDURANT® be taken with other medicines?
EDURANT® may affect the way other medicines work and other medicines may affect how EDURANT® works and may cause serious side effects. If you take certain medicines with EDURANT®, the amount of EDURANT® in your body may be too low and it may not work to help control your HIV infection, and the HIV virus in your body may become resistant to EDURANT® or other HIV medicines that are like it. To help get the right amount of medicine in your body, you should always take EDURANT® with a meal. A protein drink alone does not replace a meal.

Do not take EDURANT® if:

- Your HIV infection has been previously treated with HIV medicines
- You are taking any of the following medicines:
  - Anti-seizure medicines: carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol-XR®, Teril®, Epitol®), oxcarbazepine (Trileptal®), phenobarbital (Luminal®), phenytoin (Dilantin®, Dilantin-125®, Phenytek®)
  - Anti-tuberculosis (anti-TB) medicines: rifampin (Rifater®, Rifamate®, Rimactane®, Rifadin®), rifapentine (Priftin®)
  - Proton pump inhibitor (PPI) medicine for certain stomach or intestinal problems: esomeprazole (Nexium®, Vimovo®), lansoprazole (Prevacid®), omeprazole (Prilosec®, Zegerid®), pantoprazole sodium (Protonix®),

rabeprazole (Aciphex®)
- More than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate
- St. John's wort (Hypericum perforatum)

Especially tell your doctor if you take:

- Rifabutin (Mycobutin®, a medicine to treat some bacterial infections). Talk to your doctor or pharmacist about the right amount of EDURANT you should take if you also take rifabutin.
- Medicines used to treat HIV
- An antacid medicine that contains aluminum, magnesium hydroxide, or calcium carbonate. Take a**ntacids at least 2 hours before or at least 4 hours after you take EDURANT®**
- Medicines to block acid in your stomach, including cimetidine (Tagamet®), famotidine (Pepcid®), nizatidine (Axid®), or ranitidine hydrochloride (Zantac®). Take these medicines **at least 12 hours before or at least 4 hours after you take EDURANT®**
- Any of these medicines (if taken by mouth or injection): clarithromycin (Biaxin®), erythromycin (E-Mycin®, Eryc®, Ery-Tab®, PCE®, Pediazole®, Ilosone®), fluconazole (Diflucan®), itraconazole (Sporanox®), ketoconazole (Nizoral®), methadone (Dolophine®), posaconazole (Noxafil®), telithromycin (Ketek®), voriconazole (Vfend®)

This is not a complete list of medicines. Before starting EDURANT®,
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.

Before taking EDURANT®, also tell your healthcare professional if you have had or currently have liver problems (including hepatitis B or C), have ever had a mental health problem, are pregnant or planning to become pregnant, or breastfeeding. It is not known if EDURANT® will harm your unborn baby.
You and your healthcare professional will need to decide if taking EDURANT®
is right for you.

- **Do not breastfeed if you are taking EDURANT®**. You should not breastfeed if you have HIV because of the chance of passing HIV to your baby

What are the possible side effects of EDURANT®?

EDURANT® can cause serious side effects including:

- Depression or mood changes. Tell your doctor right away if you have any of the following symptoms: feeling sad or hopeless, feeling anxious or restless, have thoughts of hurting yourself (suicide), or have tried to hurt yourself
- Liver problems. People with a history of hepatitis B or C virus infection or who have certain liver function test changes may have an increased risk of developing new or worsening liver problems during treatment. Liver problems were also reported during treatment in some people without a history of liver disease. Your healthcare professional may need to do tests to check liver function before and during treatment
- Changes in body shape or body fat have been seen in some patients taking HIV medicines. The exact cause and long-term health effects of these conditions are not known
- Changes in your immune system (immune reconstitution syndrome).

Your immune system may get stronger and begin to fight infections. Tell your healthcare professional right away if you start having any new symptoms of infection.

Other common side effects of EDURANT® include depression, headache, trouble sleeping (insomnia), and rash.

This is not a complete list of all side effects. If you experience these or other symptoms, contact your healthcare professional right away. Do not stop taking EDURANT® or any other medications 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 see full Product Information for more details: http://www.edurant.com/sites/default/files/EDURANT-PI.pdf

About EDURANT®
Rilpivirine was developed by Janssen R&D Ireland Ltd, one of the Janssen Pharmaceutical Companies. The registered formulation of rilpivirine is a 25 mg film-coated tablet taken orally once daily. Marketed as EDURANT®, rilpivirine is indicated, in combination with other antiretrovirals (ARV), for the treatment of HIV-1 in ARV treatment-naïve adult patients. In most countries, including US and EU, this indication is further restricted to patients with a viral load 100,000 copies/ mL.

Rilpivirine is available in the United States (US) and the European Union as part of a once daily fixed dose antiretroviral combination with Gilead Sciences Inc's tenofovir and emtricitabine. This combination, known as COMPLERA® (US) or EVIPLERA®, was granted marketing authorisation from the Food and Drug Administration in August 2011, with Gilead Sciences Inc being the marketing authorisation holder in the US, and from the European Commission in November 2011, with Gilead Sciences International Ltd. being the marketing authorisation holder in Europe, Middle East and Africa.

About Janssen

At Janssen, we 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.

About TIVICAY® (dolutegravir)
TIVICAY® (dolutegravir) is an integrase inhibitor indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 in adults and children aged 12 years and older weighing at least 40 kg. Integrase inhibitors block HIV replication by preventing the viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV replication cycle and is also responsible for establishing chronic infection. It is available as a small, yellow, 50 mg tablet. Importantly, it can be taken with or without food and at any time of the day.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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 unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen R&D Ireland Ltd, any of the Janssen Pharmaceutical Companies and/or Johnson & Johnson.
Risks and uncertainties include, but are not limited to: economic factors, such as interest rate and currency exchange rate fluctuations; competition, including technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; general industry conditions including trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies.
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 our 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 nor Johnson & Johnson undertakes to update any forward-looking statements as a result of new information or future events or developments.)

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1. World Health Organization. Global summary of the AIDS epidemic. Available at: http://www.who.int/gho/hiv/en/. Last accessed June 2014.
2. Hui Dy. Effects of HIV protease inhibitor therapy on lipid metabolism. *Prog Lipid Res* 2003; 42(2):81-92.
3. World Health Organization. Global summary of the AIDS epidemic. Available at: http://www.who.int/hiv/data/2012_epi_core_en.png . Last accessed June 2014.

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