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First Investigational All Injectable Long Acting HIV Combination Regimen Study Results at 32 Weeks Announced

Injectable combinations once every 4 or 8 weeks show comparable efficacy versus daily oral combination therapy

CORK, Ireland, – November, 3, 2015 –Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), announced that Phase IIb data studying a combination regimen of two investigational long acting, injectable formulations of HIV medicines—Janssen's rilpivirine and ViiV Healthcare's cabotegravir—given together every 4 or 8 weeks show comparable efficacy to a daily oral regimen of three HIV medicines (investigational cabotegravir and two nucleoside reverse transcriptase inhibitors (NRTIs)). The full results of the study, named LATTE 2, co-funded by Janssen and ViiV Healthcare will be presented at a forthcoming scientific conference.

"Despite great progress in HIV treatments, the burden of treating HIV patients remains high. Long-acting injectable drug formulations may offer another option for HIV maintenance therapy," says Paul Stoffels, M.D. Chief Scientific Officer and Worldwide Chairman Pharmaceuticals, Johnson & Johnson. "Our hope in studying such combinations is to make HIV infection manageable with a potentially transformational all injectable regimen."

If successfully developed and approved by regulatory authorities, this regimen could offer people living with HIV who are virologically suppressed an option to switch from a standard daily regimen of three-drug therapy to a long acting all-injectable regimen that could potentially maintain viral suppression with just six or twelve injections of each drug per year.

Following the results of the proof of concept two-drug oral dose-ranging study LATTE, LATTE 2 was initiated as a phase IIb, multicentre, open label 96 week study investigating the safety and efficacy of this first all-injectable long acting combination regimen of rilpivirine and cabotegravir to maintain suppression of viral load. LATTE 2 included adults (n=309) who, after reaching virologic suppression on oral therapy with once-daily investigational oral cabotegravir 30mg + 2 NRTIs (n=286, 93%), were subsequently randomized to one of three study arms to receive either CAB LA + RPV LA injections every 4 weeks (n=115, Q4W), 8 weeks (n=115 Q8W) or continued on oral CAB + NRTIs (n=56).

Viral suppression rates (plasma HIV-1 RNA <50 c/ml by FDA snapshot analysis) for patients at 32 weeks receiving two drug maintenance therapy with investigational long acting cabotegravir (CAB LA) and long acting rilpivirine (RPV LA) whether dosed every 8 weeks (Q8W, 95%) or every 4 weeks (Q4W, 94%) were comparable to the rate observed in patients continuing with a three-drug oral regimen of investigational CAB + NRTIs (91%). Patients switching to CAB LA and RPV LA administered Q4W reported more adverse events (AEs) leading to withdrawal (5%; n=6) compared with those receiving an injection Q8W (2%; n=2) or who continued on oral CAB + NRTIs (2%, n=1). The most common AE reported by patients was injection site pain (93% of injection recipients). Two patients in the Q8W arm (none in the Q4W arm) withdrew for injection intolerance. Two patients met protocol defined virologic failure criteria, Q8W (n=1), oral (n=1); neither patient had evidence of resistance at failure.

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 three-drug oral therapy contains three active components taken daily: a backbone of two NRTIs, plus either a non-nucleoside reverse transcriptase inhibitor, protease inhibitor (PI) or integrase inhibitor (INI).

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About EDURANT® (Rilpivirine)

EDURANT® (rilpivirine) is a prescription HIV medicine that is used with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) in patients:

- 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 12 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 antacids 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:

- Severe skin rash and allergic reactions. Call your doctor right away if you get a rash. Stop taking EDURANT® and seek medical help right away if you get a rash with any of the following symptoms: severe allergic reaction causing swelling of the face, eyes, lips, mouth, tongue, or throat (which may lead to difficulty swallowing or breathing); mouth sores or blisters on your body; inflamed eye (conjunctivitis); fever; dark urine; or pain on the right side of the stomach area (abdominal pain)
- 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 side effects of prescription drugs to the FDA. Visit 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 accompanying full Product Information for more details.

About cabotegravir

Cabotegravir is an investigational integrase strand inhibitor (INSTI) and analogue of dolutegravir (TIVICAY®). Cabotegravir is being developed by ViiV Healthcare for the treatment and prevention of HIV and is currently being evaluated as a once-daily oral tablet formulation and as a LA nanosuspension formulation for intramuscular (IM) injection.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

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.

References

1. World Health Organization. Global summary of the AIDS epidemic. Available at: http://www.who.int/gho/hiv/en/. Last accessed October 2015.
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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 October 2015.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 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 Sciences Ireland UC and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in new product development, including uncertainty of clinical success and obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including global health care reforms; and 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 28, 2014, 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 undertakes to update any forward-looking statement as a result of new information or future events or developments.

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