NEWS RELEASE

Janssen to Progress Collaboration with ViiV Healthcare to Develop the First Long Acting Two Drug Injectable Regimen for Treatment of HIV Infection

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CORK, Ireland, January 7, 2016 /PRNewswire/ --

Results from ongoing phase IIb Week 32 study show that if successfully developed and approved, people living with HIV could potentially maintain viral suppression

Janssen Sciences Ireland UC (Janssen), today formalized its collaboration with ViiV Healthcare on phase III development and commercialization of a two drug regimen of two long acting, all-injectable formulations of rilpivirine (a non-nucleoside reverse transcriptase inhibitor by Janssen) and cabotegravir (ViiV Healthcare).

(Logo: **http://photos.prnewswire.com/prnh/20140324/NY88746LOGO**)

Janssen and ViiV Healthcare have been working together on this regimen, through a number of clinical trial agreements, for several years. Under this new agreement, the phase III development, to evaluate the efficacy, safety and tolerability of the regimen, will be led by ViiV Healthcare with support from Janssen. Each company will manufacture and supply their individual drug formulations following successful phase III completion and regulatory outcomes.

"Despite great progress in developing HIV treatments, the day-to-day burden of managing HIV remains high and poses challenges to ensure people living with HIV maintain an undetectable viral load," says Paul Stoffels, Chief Scientific Officer, Johnson & Johnson and Worldwide Chairman, Janssen Pharmaceutical Companies. "We are committed to making a real difference for those affected by HIV. The prospect of developing new therapies, such as

long acting formulations which are broadly accessible, may offer hope to the many millions affected by HIV around the world."

At week 32, in an ongoing phase IIb study (LATTE 2, NCT02120352), the investigational long acting, all-injectable combination regimen, given every 4 or 8 weeks, showed comparable efficacy to a daily oral regimen of three HIV medicines (investigational cabotegravir and two nucleoside reverse transcriptase inhibitors (NRTIs)). If successfully developed and approved by regulatory authorities, people living with HIV who are virologically suppressed could be offered an alternative option to the standard oral daily regimen* of three drug therapy.

"While we work toward our long-term goal of developing a preventative HIV vaccine, we are excited to be able to continue to support people living with HIV through innovative improvements," said Wim Parys, Head of R&D, Global Public Health, Janssen. "Through this collaboration, we have the potential to develop the first long acting, all-injectable two drug regimen as an innovative option for HIV maintenance therapy."

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

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

More information on the Phase IIb LATTE 2 study

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 &#60 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 due to injection intolerance. Two patients met protocol-defined virologic failure criteria, Q8W (n=1), oral (n=1); neither patient had evidence of resistance at failure.

Results of the LATTE 2 study, co-funded by Janssen and ViiV Healthcare, will be presented at a forthcoming scientific conference.

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 **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** for more detail.

About cabotegravir

Cabotegravir is an investigational integrase strand transfer 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 long-acting nanosuspension formulation for intramuscular (IM) injection.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

Janssen Sciences Ireland UC is one of 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.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding a new collaboration and 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 Johnson & Johnson. Risks and uncertainties include, but are not limited to: the potential that the expected benefits and opportunities related to the collaboration may not be realized or may take longer to realize than expected; 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 **http://www.sec.gov**, **http://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.

Press Contacts:

Daniel De Schryver
+49-173-76-89-149
ddschryv@its.jnj.com

Ronan Collins
+47-488-425-00
rcollin5@its.jnj.com

Investor Contacts:

Louise Mehrotra
+1(732)524-6491
Lesley Fishman
+1(732)524-3922

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