FDA Approves INTELENCE® (etravirine) Tablets for Treatment-Experienced Pediatric Patients with HIV-1, Following Priority Review

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[Titusville, NJ, March 27, 2012] - Janssen Therapeutics, Division of Janssen Products, LP, announced today the U.S. Food and Drug Administration (FDA) has approved INTELENCE® (etravirine) to be administered in combination with other antiretroviral (ARV) medications for treatment of human immunodeficiency virus 1 (HIV-1) in treatment-experienced pediatric patients (6 years to <18 years old) who are experiencing virologic failure with HIV-1 strains resistant to a non-nucleoside reverse transcriptase inhibitor (NNRTI) and other ARVs.

This approval, which follows FDA priority review of the company's supplemental New Drug Application, expands the INTELENCE indication and makes it the only NNRTI indicated for this use in both treatment-experienced children and adults with resistance to an NNRTI and other ARVs. The approval includes a new 25mg dose to allow for weight-based dosing in pediatric patients (6 years to <18 years old and weighing at least 16kg or 35.2 lbs). The 25mg tablet is expected to be available in the first half of May.

"This indication fulfills an important need in the U.S. among treatment-experienced young children and adolescents living with HIV," said David Anderson, M.D., Medical Director at Janssen Therapeutics. "This approval also expands the treatment options INTELENCE offers, and reinforces our company's commitment to serving the diverse needs of the HIV treatment community."

INTELENCE should be taken orally following a meal. For patients unable to swallow INTELENCE tablets whole, the tablets may be dispersed in a glass of water. Once the tablets are dispersed in water, they can be added to other liquids such as milk or orange juice. The use of grapefruit juice, warm liquids or carbonated beverages should be avoided.

The approval is based on 24-week data from the PIANO (**P**ediatric trial with **I**NTELENCE as an **A**ctive **N**NRTI **O**ption) study, which evaluated the pharmacokinetics, safety, tolerability and efficacy of INTELENCE in combination with other ARVs in antiretroviral treatment-experienced pediatric patients 6 years to <18 years of age.

About INTELENCE
In January 2008, the FDA granted accelerated approval to INTELENCE for use in combination with other ARVs for the treatment of HIV-1 infection in treatment-experienced adult patients who have evidence of viral replication and HIV-1 strains resistant to an NNRTI and other antiretroviral agents. In November 2009, INTELENCE received traditional FDA approval based on 48-week data from the DUET 1 and DUET 2 studies.

In treatment-experienced adult and pediatric patients, the following points should be considered when initiating therapy with INTELENCE:

" Treatment history and resistance testing should guide the use of INTELENCE due to concerns for potential cross-resistance.

- In patients who have experienced virologic failure on an NNRTI-containing regimen, do not use INTELENCE in combination with only N[t]RTIs.
- The use of other active antiretroviral agents with INTELENCE is associated with an increased likelihood of treatment response.
- The safety and efficacy of INTELENCE have not been established in pediatric patients less than 6 years of age or in treatment-naïve adult or pediatric patients.

INTELENCE does not cure HIV-1 infection or AIDS. You must stay on continuous HIV therapy to control HIV infection and decrease HIV-related illnesses.

About the PIANO Study
The 24-week data from the PIANO (**P**ediatric Trial with **I**NTELENCE as an **A**ctive **N**NRTI **O**ption) study was presented at the 2011 International AIDS Conference in Rome. The data were from a single-arm, Phase 2 trial evaluating the pharmacokinetics, safety, tolerability, and efficacy of INTELENCE in 101 antiretroviral treatment-experienced HIV-1 infected pediatric subjects 6 years to <18 years of age and weighing at least 35.2 lbs.

The study enrolled subjects on a stable but virologically failing antiretroviral treatment regimen, with a confirmed HIV-1 RNA plasma viral load ? 500 copies/mL. Sensitivity of the virus to INTELENCE at screening was required. The median baseline plasma HIV-1 RNA was 3.9 log10 copies/mL, and the median baseline CD4 cell count was 385 x 106 cells/mm3.

At Week 24, the virologic response rate was evaluated in pediatric subjects receiving INTELENCE in combination with other antiretroviral agents. Virologic response was defined as achieving an undetectable viral load (<50 HIV 1 RNA copies/mL).

At Week 24, 52% of all pediatric subjects had an undetectable viral load < 50 HIV-1 RNA copies/mL. The proportion of pediatric subjects with < 400 HIV-1 RNA copies/mL was 67%. The mean CD4 cell count increase from baseline was 112 x 106 cells/mm3.

The frequency, type and severity of adverse drug reactions in pediatric subjects were comparable to those observed in adults, except for rash which was observed more frequently than in adults. Rash (? grade 2) occurred in 15% of pediatric subjects. Most often, rash was mild to moderate, of macular/papular type, and occurred in the second week of therapy. Rash was mostly self-limiting and generally resolved within 1 week on continued therapy. The discontinuation rate for rash was 4%. Rash occurred more commonly in females than males.

About INTELENCE
INTELENCE is a prescription HIV medicine that is used with other HIV medicines to treat HIV (human immunodeficiency virus) infection in adults and children 6 years of age and older. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). INTELENCE is a type of HIV medicine called a non-nucleoside reverse transcriptase inhibitor (NNRTI), also known as a non-nuke.

INTELENCE must be taken in combination with other HIV medicines. INTELENCE is used in people who are already taking or have taken NNRTI and other HIV medicines and these medicines are not controlling their HIV infection.

The use of other medicines active against your HIV in combination with INTELENCE may increase the likelihood of your overall treatment response. If a non-nuke regimen has stopped working for you, INTELENCE should not be taken with only nucleoside/nucleotide reverse transcriptase inhibitors, also known as nukes. Your healthcare professional will work with you to find the right combination of other HIV medicines.

It is important that you remain under the care of your healthcare professional during treatment with INTELENCE.

It is not known if INTELENCE is safe and effective in children less than 6 years of age.

INTELENCE does not cure HIV infection or AIDS. You must stay on continuous HIV therapy to control your HIV infection and decrease HIV-related illnesses.

Ask your healthcare professional if INTELENCE is right for you.

Important Safety Information
What are the possible side effects of INTELENCE?
INTELENCE can cause serious side effects including:

Severe skin rash and allergic reactions. Skin rash in general is a common side effect of INTELENCE, and was seen more commonly in children than adults in clinical studies. Rash can be serious and may potentially lead to death. If you get a rash with any of the following symptoms, stop taking INTELENCE and call your healthcare professional right away: hives or sores in your mouth, or your skin blisters and peels, trouble swallowing or breathing, swelling of your face, eyes, lips, tongue, or throat, fever, yellowing of the skin or whites of the eyes, dark urine, or pain on the right of the stomach-area (abdominal pain).

Changes in body shape or body fat. 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. In adults, common side effects of INTELENCE include tingling, numbness, or pain in hands or feet.

In children, diarrhea is a common side effect of INTELENCE. This is not a complete list of all side effects. If you experience these or other symptoms, contact your healthcare professional right away.

What should I tell my doctor before I take INTELENCE?
Before taking INTELENCE, tell your healthcare professional if you have liver problems, including hepatitis B or C have any other medical conditions, or if you are pregnant, planning to become pregnant, or breastfeeding.

It is not known if INTELENCE can cause harm to your unborn baby. Do not breastfeed if you are taking INTELENCE. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Taking INTELENCE with certain medicines may cause serious side effects or may result in loss of its effectiveness (which could increase your risk for developing resistance to INTELENCE or other HIV medicines that are like it).

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, available at http://www.intelence-info.com/patient-and-product-information.

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 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.

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 Therapeutics, Division of Janssen Products, LP and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; 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 healthcare products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the healthcare industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Janssen Therapeutics, Division of Janssen Products, LP nor Johnson & Johnson undertakes to update any forward-looking statements as a result of new information or future events or developments.