

FDA APPROVES INTELENCE™ (etravirine) FOR HIV COMBINATION THERAPY

--INTELENCE is the first NNRTI to show antiviral activity in patients with NNRTI-resistant virus--

Bridgewater, NJ, January 18, 2008 – The U.S. Food and Drug Administration (FDA) has granted accelerated approval to the anti-HIV medication INTELENCE (etravirine) tablets – the first non-nucleoside reverse transcriptase inhibitor (NNRTI) to show antiviral activity in treatment-experienced adult patients with HIV resistant to a NNRTI and other antiretroviral (ARV) agents. INTELENCE, also known as TMC125, was developed by Tibotec Pharmaceuticals, Ltd. and will be marketed in the U.S. by Tibotec Therapeutics, a division of Ortho Biotech Products, L.P.

“NNRTIs have been used in HIV combination therapy for more than a decade, but their use has been limited by cross-resistance within the class. Resistance to one NNRTI generally meant resistance to all NNRTIs,” said Richard Haubrich, M.D., Professor of Medicine, Division of Infectious Diseases, University of California, San Diego, and investigator in the INTELENCE Phase 3 DUET studies. “Etravirine breaks new ground in the NNRTI class, and provides a new option to thousands of treatment-experienced patients with NNRTI-resistant HIV.”

INTELENCE, in combination with other antiretroviral agents, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced adult patients, who have evidence of viral replication and HIV-1 strains resistant to a NNRTI and other ARV agents.

This indication is based on Week 24 analyses from two randomized, double-blind, placebo-controlled trials of INTELENCE. Both studies were conducted in clinically advanced, three-class antiretroviral (NNRTI, N[t]RTI, PI) treatment-experienced adults.

The following points should be considered when initiating therapy with INTELENCE:

- Treatment history and, when available, resistance testing, should guide the use of INTELENCE.
- The use of other active antiretroviral agents with INTELENCE is associated with an increased likelihood of treatment response.

- In patients who have experienced virologic failure on an NNRTI-containing regimen, do not use INTELENCE in combination with only N[t]RTIs.
- The risks and benefits of INTELENCE have not been established in pediatric patients or in treatment-naïve adult patients.

FDA accelerated approval procedures allow for earlier approval of drugs that provide a meaningful therapeutic benefit over existing treatment for serious or life-threatening diseases. The INTELENCE approval is based on the 24-week analysis of HIV viral load and CD4+ cell counts from the pooled analysis of the DUET-1 and -2 studies. Longer-term data will be required before the FDA can consider traditional approval for INTELENCE.

“It is very inspiring to our R&D organization to see an additional compound so quickly emerge from our pipeline and reach patients who need it,” said Roger Pomerantz, MD, FACP, President, Tibotec Research and Development. “With one of the most robust virology research and development programs in the industry, we are dedicated to continuing to deliver innovative approaches in HIV management in the years to come.”

“The addition of INTELENCE following the launch of our first antiretroviral just two years ago is a significant milestone for Tibotec Therapeutics,” said Glenn Mattes, President, Tibotec Therapeutics. “In partnership with Tibotec R&D, we are committed to continuing to bring new options to people living with HIV.”

The NNRTI Class

INTELENCE is the first new NNRTI to be introduced in nearly 10 years. It is also the first NNRTI to show antiviral activity in patients with NNRTI-resistant virus. NNRTIs block reverse transcriptase, a key enzyme the HIV virus uses to replicate. NNRTI drug resistance occurs when HIV develops mutations that partially or completely stop the NNRTI from binding to the reverse transcriptase enzyme, causing the drug to lose effectiveness. As with other HIV medications, patients can develop resistance to INTELENCE; for more information see the resistance section below.

DUET-1 and -2 Study Design

The DUET-1 and -2 studies, identical in design but conducted in different regions, assessed the 24-week efficacy and safety of INTELENCE in combination with a background regimen (BR) in treatment-experienced adult HIV-1 patients with documented evidence of NNRTI and PI resistance. They were large randomized, controlled studies with a primary endpoint of less than 50 copies/mL (known as undetectable viral load). IAS-USA treatment guidelines define less than 50 copies/mL as the goal of therapy for treatment-experienced patients when two or more potent drugs are identified.

Patients with HIV-1 who were eligible for the DUET studies had a viral load of greater than 5,000 copies/mL while on a stable antiretroviral therapy regimen for at least eight weeks and had evidence of at least one NNRTI-resistance-associated mutation, either at screening or from prior resistance tests, as well as evidence of three or more primary PI mutations (D30N, V32I, L33F, M46I/L, I47A/V, G48V, I50L/V, V82A/F/L/S/T, I84V, N88S, or L90M) at screening.

DUET-1 and -2 Efficacy

Participants in the DUET studies were randomized to receive INTELENCE 200 mg twice daily (599 patients) or placebo (604 patients), each given in addition to a BR. For all patients, the BR included darunavir/ritonavir, plus at least two investigator-selected antiretroviral drugs (N(t)RTIs with or without enfuvirtide).

The 24-week pooled analysis of the DUET studies showed the following results for INTELENCE plus BR vs. placebo plus BR:

- Significantly more patients in the INTELENCE arm achieved undetectable viral load (less than 50 copies/mL); 59.8 percent vs. 40.2 percent [$p < 0.0001$].
- Significantly greater mean increase in CD4+ cell count from baseline; mean increase of 81 vs. 64 cells/mm³ [$p = 0.0022$].

The results of DUET-1 and DUET-2 were published separately in two articles in the July 7, 2007 issue of *The Lancet*, and the pooled analysis from the DUET studies was presented at the 47th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in September 2007.

DUET-1 and -2 Resistance

- The presence of K103N, which was the most prevalent NNRTI substitution in DUET-1 and -2 studies at baseline, did not affect the response in the INTELENCE arm.
- The presence at baseline of the substitutions V179D, V179F, V179T, Y181V, or G190S was associated with a decreased virologic response to INTELENCE.
- In the DUET-1 and -2 studies, the presence at baseline of three or more 2007 IAS-USA-defined NNRTI substitutions (V90I, A98G, L100I, K101E/P, K103N, V106A/I/M, V108I, V179D/F, Y181C/I/V, Y188C/H/L, G190A/S, P225H) resulted in a decreased virologic response to INTELENCE.
- For patients in the DUET-1 and -2 studies experiencing virologic failure on an INTELENCE-containing regimen, the substitutions that occurred most commonly were V179F, V179I, Y181C, and Y181I which usually emerged in a background of multiple other NNRTI resistance-associated substitutions. Other NNRTI-resistance associated substitutions which emerged in patients on INTELENCE treatment in < 10% of the virologic failure isolates included K101E, K103N, V106I/M, V108I, Y188L, V189I, G190S/C and R356K.
- Cross-resistance to delavirdine, efavirenz, and/or nevirapine is expected after virologic failure with an INTELENCE-containing regimen.

DUET-1 and -2 Tolerability

In the DUET-1 and -2 studies, the most common adverse events (>10 percent) of any intensity that occurred at a higher rate than placebo were rash (16.9 percent vs. 9.3 percent) and nausea (13.9 percent vs. 11.1 percent). The most common treatment-emergent adverse reactions (Grade 2-4) that occurred in greater than or equal to two percent of patients receiving an INTELENCE-containing regimen were diarrhea, nausea, abdominal pain, vomiting, fatigue, peripheral neuropathy, headache, rash, and hypertension.

Additional Important Safety Information

INTELENCE does not cure HIV infection or AIDS, and does not prevent passing HIV to others.

- Severe and potentially life-threatening skin reactions, including Stevens-Johnson Syndrome, hypersensitivity reaction, and erythema multiforme, have occurred (<0.1 percent) in patients taking INTELENCE. Treatment with INTELENCE should be discontinued and appropriate therapy initiated if severe rash develops.

In general, in clinical trials, rash was mild to moderate, occurred primarily in the second week of therapy, and was infrequent after Week 4. Rash generally resolved within 1-2 weeks on continued therapy. Discontinuation rate due to rash was 2 percent.

- Redistribution and/or accumulation of body fat have been observed in patients receiving antiretroviral (ARV) therapy. The causal relationship, mechanism, and long-term consequences of these events have not been established.
- Immune reconstitution syndrome has been reported in patients treated with ARV therapy, including INTELENCE.
- INTELENCE should be used with caution in patients with severe hepatic impairment (Child-Pugh class C) as pharmacokinetics of INTELENCE have not been evaluated in these patients.

Drug Interactions

- INTELENCE should not be co-administered with the following ARVs: tipranavir/ritonavir, fosamprenavir/ritonavir, atazanavir/ritonavir, full-dose ritonavir (600 mg bid), protease inhibitors administered without ritonavir, and other NNRTIs.
- INTELENCE should not be co-administered with carbamazepine, phenobarbital, phenytoin, rifampin, rifapentine, rifabutin (when part of a regimen containing protease inhibitor/ritonavir) or products containing St. John's wort (*Hypericum perforatum*).
- INTELENCE and lopinavir/ritonavir should be co-administered with caution.
- Coadministration of INTELENCE with other agents such as substrates, inhibitors, or inducers of CYP3A4, CYP2C9, and/or CYP2C19 may alter the therapeutic effect or adverse events profile of INTELENCE or the co-administered drug(s). **This is not a complete list of potential drug interactions.**

Please see full Prescribing Information for more details, available at www.INTELENCE-info.com.

Patient Access to INTELENCE

INTELENCE is expected to be available at the wholesale level in the U.S. within one week.

Martin Delaney of the Fair Pricing Coalition said, "Tibotec Therapeutics continues to demonstrate real leadership in the pharmaceutical industry by pricing INTELENCE fairly and

responsibly. We applaud Tibotec's responsible corporate behavior and expect to see the drug quickly accepted on all formularies."

"With the introduction of INTELENCE, Tibotec Therapeutics has demonstrated exceptional leadership in working with the HIV community in an effort to address pricing and access issues. Tibotec has repeatedly recognized the necessity of responsibly pricing HIV products and should be commended for its leadership in this regard," said Lynda Dee from the AIDS Treatment Activist Coalition.

Tibotec Therapeutics

Tibotec Therapeutics, a division of Ortho Biotech Products, L.P., headquartered in Bridgewater, N.J., is dedicated to delivering innovative virology therapeutics that help healthcare professionals address serious unmet needs in people living with HIV.

Tibotec Pharmaceuticals Ltd.

Tibotec Pharmaceuticals Ltd., based in Cork, Ireland, is a pharmaceutical research and development company. The Company's main research and development facilities are in Mechelen, Belgium with offices in Yardley, PA. Tibotec is dedicated to the discovery and development of innovative HIV/AIDS drugs and anti-infectives for diseases of high unmet medical need.

Applications for approval of INTELENCE have also been submitted to the European Agency for the Evaluation of Medicinal Products (EMA) and with regulatory authorities in Canada, Switzerland, Russia and Australia.

Ortho Biotech Products, L.P. and Tibotec Pharmaceuticals Ltd. are subsidiaries of Johnson & Johnson.

Forward Looking Statement

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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 Tibotec

Pharmaceuticals Ltd.'s expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. 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 December 31, 2006. 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 Tibotec Pharmaceuticals Ltd. or Johnson & Johnson. Tibotec Pharmaceuticals Ltd. does not undertake to update any forward-looking statements as a result of new information or future events or developments.

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