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U.S. Food and Drug Administration (FDA) Approves PREZISTA® Once-Daily as Part of Combination Therapy for Treatment-Naïve Adults with HIV-1
—PREZISTA also granted traditional approval—

[Bridgewater, NJ, October 22, 2008] – The FDA has granted PREZISTA® (darunavir) tablets, a protease inhibitor, approval for an expanded indication for once-daily dosing as part of HIV combination therapy in treatment-naïve adults (those who have never taken HIV medication before). The FDA also granted traditional (full) approval to PREZISTA as twice-daily for use in treatment-experienced adult patients. PREZISTA was developed by Tibotec Pharmaceuticals and is marketed in the U.S. by Tibotec Therapeutics, a division of Ortho Biotech Products, L.P.

In June 2006, PREZISTA received accelerated approval for use in combination with other antiretrovirals (ARVs) in treatment-experienced adult patients, such as those with HIV-1 that is resistant to more than one protease inhibitor. Following today’s approval, PREZISTA, co-administered with 100 mg ritonavir (PREZISTA/r), and with other antiretroviral agents, is indicated for the treatment of human immunodeficiency virus (HIV-1) infection.

This indication is based on analyses of plasma HIV RNA levels and CD4+ cell counts from two controlled phase 3 trials of 48 weeks duration in antiretroviral treatment-naïve and treatment-experienced patients and two controlled phase 2 trials of 96 weeks duration in clinically advanced, treatment-experienced patients.

In treatment-experienced patients, the following points should be considered when initiating therapy with PREZISTA/r: treatment history and, when available, genotypic or
phenotypic testing, should guide the use of PREZISTA/r. The use of other active agents with PREZISTA/r is associated with a greater likelihood of treatment response.

The risks and benefits of PREZISTA/r have not been established in pediatric patients. No clinical studies have demonstrated the effect of PREZISTA/r on clinical progression of HIV-1.

The traditional approval is based on 48-week data from the ARTEMIS and TITAN phase 3 non-inferiority studies and 96-week safety and efficacy data from the phase 2b POWER studies. Both ARTEMIS and TITAN studied the efficacy and safety of PREZISTA/r vs. lopinavir/r in combination with other ARVs.

The ARTEMIS study was conducted in treatment-naïve HIV-1-infected adult patients with an HIV viral load greater than or equal to 5,000 copies/mL. TITAN was conducted in lopinavir/r-naïve, treatment-experienced adult patients and the POWER studies were conducted in clinically advanced, treatment-experienced adult patients with a high level of protease inhibitor resistance. In the TITAN and POWER studies, patients had evidence of ongoing HIV-1 replication despite antiretroviral therapy.

"Over the past two years, PREZISTA has made an important contribution to the care of treatment-experienced adults with HIV. The medical community welcomes the news that PREZISTA is now available as an effective, once-daily option as part of combination therapy for adults who have never taken HIV medications before,” said Calvin J. Cohen, M.D., M.Sc., clinical investigator and Research Director at Community Research Initiative of New England and Harvard Vanguard Medical Associates.

Forty-eight week results from ARTEMIS in treatment-naïve adults:

- Eighty-four percent of patients in the PREZISTA/r arm (n=343) reached an undetectable viral load (<50 copies/mL) vs. 78 percent of patients in the lopinavir/r arm (n=346) (study demonstrated non-inferiority, p = not statistically significant).
The median change in CD4+ cell count from baseline was similar between PREZISTA/r and lopinavir/r arms (137 cells per cubic millimeter vs. 141 cells per cubic millimeter) (p = not statistically significant).

Low rates of gastrointestinal adverse drug reactions (ADRs) were observed in the PREZISTA/r arm.

- Gastrointestinal ADRs of at least moderate intensity (≥ Grade 2) in ≥ 1 percent of patients were: diarrhea (6 percent vs. 13 percent), abdominal pain (4 percent vs. 5 percent), nausea (3 percent vs. 3 percent), vomiting (2 percent vs. 3 percent) respectively for PREZISTA/r vs. lopinavir/r arm.

In treatment-naïve adult patients, the most common ADRs (≥2 percent) reported of at least moderate intensity (≥Grade 2) in the PREZISTA/r arm were diarrhea (6 percent), headache (5 percent), abdominal pain (4 percent), nausea (3 percent), vomiting (2 percent), and rash (2 percent).

Forty-eight week results from TITAN in lopinavir/r-naïve, treatment-experienced adults:

- Seventy-seven percent of patients in the PREZISTA/r arm (n=298) vs. 67 percent of patients in the lopinavir/r arm (n=297) reached less than 400 copies/mL, (study demonstrated non-inferiority, p<0.0001).

In treatment-experienced adult patients, the most common ADRs (≥2 percent) reported of at least moderate intensity (≥Grade 2) in the PREZISTA/r arm were diarrhea (12 percent), nausea (7 percent), rash (6 percent), abdominal pain (5 percent), vomiting (4 percent), asthenia (3 percent), headache (2 percent), abdominal distension (2 percent), and dyspepsia (2 percent).

Ninety-six week results from POWER in clinically advanced, treatment-experienced adults:

- Fifty-seven percent of patients in the PREZISTA/r arm (n=131) vs. 10 percent of patients in the comparator protease inhibitor arm (n=124) achieved a virologic response defined as greater than or equal to a 1.0 log_{10} reduction (90 percent reduction) in viral load from baseline.
The latest recommendations from the International AIDS Society-USA Panel, which were published in the August 6, 2008 issue of the *Journal of the American Medical Association*, recommend PREZISTA as one of the initial treatment options as part of combination therapy for adults living with HIV.

“Tibotec is proud to reach this important milestone that makes PREZISTA available to those who are just starting HIV treatment for the first time,” said Glenn Mattes, President of Tibotec Therapeutics. “We look forward to continuing to provide treatment options that will add to the arsenal of anti-HIV therapies.”

**Dosing**
Recommended dosing for treatment-naïve adult patients is 800 mg (two 400 mg tablets) taken with 100 mg ritonavir once daily. The new 400 mg tablet will be available by November 1. For treatment-experienced adult patients, the dosing for PREZISTA remains 600 mg taken with 100 mg ritonavir twice daily. PREZISTA must be taken with food and in combination with other ARVs. PREZISTA/r is not recommended for use in patients with severe hepatic impairment.

Tibotec will discontinue production of the 300 mg tablet of PREZISTA as a result of decreasing demand following the introduction of the 600 mg tablet earlier this year. The 600 mg tablet allows treatment-experienced adult patients who currently take two 300 mg of PREZISTA twice daily to now take one 600 mg tablet twice daily.

**ARTEMIS**
The sNDA submission included the 48-week findings of ARTEMIS (*AntiRetroviral Therapy with TMC114 Examined In naïve Subjects*), an ongoing phase 3, randomized, controlled, open-label study that compared the efficacy and safety of PREZISTA/r with lopinavir/r in treatment-naïve HIV-1-infected adult patients. Patients with HIV-1 viral load ≥ 5,000 copies/mL were randomized to receive a PREZISTA/r dose of 800 mg/100 mg once daily, or lopinavir/r given as 400 mg/100 mg twice daily or 800 mg/200 mg once daily. All patients received a fixed dose background regimen of tenofovir and
emtricitabine once daily. The primary objective was to demonstrate non-inferiority of PREZISTA/r compared with lopinavir/r in virologic response (confirmed HIV-1 viral load <50 copies/mL) at week 48.

At week 48, six percent of patients in the PREZISTA/r arm experienced virological failure vs. 10 percent of patients in the lopinavir/r arm.

**TITAN**
The sNDA submission also included 48-week data from TITAN (TMC114/r In Treatment-experienced pAtients Naïve to lopinavir/ritonavir), a phase 3, randomized, controlled, open-label study, comparing the efficacy and safety of a PREZISTA/r dose of 600 mg/100 mg twice daily with lopinavir/r 400 mg/100 mg twice daily, each with an optimized background regimen (OBR) of at least two antiretrovirals (NRTIs with or without NNRTIs), in treatment-experienced HIV-1-infected adult patients who were lopinavir/r-naïve. All patients had an HIV viral load greater than or equal to 1,000 copies/mL, and had been receiving antiretroviral therapy for at least 12 weeks. The primary objective was to demonstrate non-inferiority of PREZISTA/r compared with lopinavir/r in virologic response (HIV-1 viral load <400 copies/mL) at week 48.

At week 48, 11 percent of patients in the PREZISTA/r arm experienced virological failure vs. 21 percent of patients in the lopinavir/r arm.

**POWER**
The sNDA submission also included 96-week data from POWER (TMC114-C213 and TMC114-C202), two controlled, phase 2b trials in clinically advanced, treatment-experienced adults with a high level of protease inhibitor resistance. Patients with HIV-1 viral load > 1000 copies/mL, who had one or more primary protease inhibitor mutations, and were failing a protease inhibitor-based regimen, were randomized to receive PREZISTA/r 600 mg/100 mg twice daily plus OBR (at least two NRTIs with or without enfuvirtide) versus an investigator-selected ritonavir-boosted comparator protease inhibitor plus OBR.
At week 96, 29 percent of patients in the PREZISTA/r arm experienced virological failure vs. 80 percent of patients in the comparator protease inhibitor arm.

**Important Safety Information**

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

Coadministration of PREZISTA/r is contraindicated with drugs that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events (e.g., dihydroergotamine, ergonovine, ergotamine, methylergonovine, cisapride, pimozide, oral midazolam, triazolam, lovastatin, or simvastatin).

Coadministration of PREZISTA/r is also contraindicated with rifampin and products containing St. John’s wort (*Hypericum perforatum*) because this may cause significant decrease in plasma concentration of darunavir, resulting in loss of therapeutic effect and development of resistance.

Coadministration is not recommended with indinavir, lopinavir/ritonavir, saquinavir, and pravastatin.

Caution should be used when prescribing agents such as sildenafil, vardenafil, tadalafil, or other substrates, inhibitors, or inducers of CYP3A in patients receiving PREZISTA/r. **This list of potential drug interactions is not complete.**

PREZISTA must be co-administered with 100 mg ritonavir and food to achieve the desired antiviral effect. Failure to correctly administer PREZISTA with ritonavir and food may result in a loss of efficacy of darunavir. Please refer to ritonavir prescribing information for additional information on precautionary measures.
Drug-induced hepatitis (e.g., acute hepatitis, cytolytic hepatitis) has been reported with PREZISTA/r. During the clinical development program (n=3063), hepatitis has been reported in 0.5 percent of patients receiving combination therapy with PREZISTA/r. Patients with pre-existing liver dysfunction, including chronic active hepatitis B or C, have an increased risk for liver function abnormalities, including severe hepatic adverse events.

Post-marketing cases of liver injury, including some fatalities, have been reported. A causal relationship with PREZISTA/r therapy has not been established.

Appropriate laboratory testing should be conducted prior to initiating therapy with PREZISTA/r and patients should be monitored during treatment. Increased AST/ALT monitoring should be considered in patients with underlying chronic hepatitis, cirrhosis, or in patients who have pre-treatment elevations of transaminases, especially during the first several months of PREZISTA/r treatment. Evidence of new or worsening liver dysfunction (including clinically significant elevation of liver enzymes and/or symptoms such as fatigue, anorexia, nausea, jaundice, dark urine, liver tenderness, hepatomegaly) in patients on PREZISTA/r should prompt consideration of interruption or discontinuation of treatment.

Cases of severe skin rash (0.4 percent) and Stevens-Johnson syndrome (<0.1 percent) have been reported in subjects receiving PREZISTA. In clinical trials (n=3063), rash (all grades, generally mild-to-moderate, regardless of causality) occurred in 10.3 percent of subjects treated with PREZISTA. Discontinuation due to rash was 0.5 percent. PREZISTA should be discontinued if severe rash develops.

PREZISTA should be used with caution in patients with known sulfonamide allergy.

New-onset or exacerbations of pre-existing diabetes mellitus, hyperglycemia, and increased bleeding in hemophiliacs have been reported in patients receiving protease inhibitors. Initiation or dose adjustments of insulin or oral hypoglycemic agents may be
required. A causal relationship between protease inhibitors and these events has not been established.

Redistribution and/or accumulation of body fat have been observed in patients receiving 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.

The potential for HIV cross-resistance among protease inhibitors has not been fully explored in PREZISTA/r treated patients.

PREZISTA/r is not recommended for use in patients with severe hepatic impairment. There are no pharmacokinetic or safety data available in patients with severe hepatic impairment.

PREZISTA should be used during pregnancy only if the potential benefit justifies the potential risk. No adequate and well-controlled studies have been conducted in pregnant women.

In treatment-naïve adult patients receiving a PREZISTA/r-containing regimen, the most common adverse drug reactions (≥2 percent) reported of at least moderate to severe intensity (≥ Grade 2) were diarrhea (6 percent), headache (5 percent), abdominal pain (4 percent), nausea (3 percent), vomiting (2 percent), and rash (2 percent).

In treatment-experienced adult patients receiving a PREZISTA/r-containing regimen, the most common adverse drug reactions (≥2 percent) reported of at least moderate to severe intensity (≥ Grade 2) were diarrhea (12 percent), nausea (7 percent), abdominal pain (5 percent), rash (6 percent), vomiting (4 percent), asthenia (3 percent), headache (2 percent), abdominal distension (2 percent), and dyspepsia (2 percent).
This is not a complete list of all adverse drug reactions reported with the use of PREZISTA/r.

Please see full Prescribing Information for more details. A copy of full Prescribing Information can be obtained by visiting PREZISTA.com.

About Tibotec Pharmaceuticals
Tibotec Pharmaceuticals, 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.

About 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.

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

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Johnson & Johnson’s Annual Report on Form 10-K for the fiscal year ended December 30, 2007. 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. The Company does not undertake to update any forward-looking statements as a result of new information or future events or developments.)

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