



Once-Daily Prezista® (darunavir) for Treatment-Naïve Adults with HIV-1 Receives Approval in the European Union as Part of Combination Therapy

--PREZISTA Now Indicated for Adults Living with HIV at All Phases of Treatment--

Cork, Ireland: 3rd February 2009 - Tibotec Pharmaceuticals announced today that the European Commission approved once-daily dosing of 800 mg PREZISTA® (darunavir), a protease inhibitor, with low-dose ritonavir as part of combination therapy in treatment-naïve adults (those who have never taken HIV medication before). This approval broadens the previous indication of darunavir for treatment-experienced HIV-1 patients. Darunavir was developed by Tibotec Pharmaceuticals and is marketed in Europe by Tibotec, a division of Janssen-Cilag.

"We welcome PREZISTA's availability as an effective, once-daily option for adults who have never taken HIV medication before. It has made a significant contribution in the care of treatment-experienced adults with HIV for the last two years, and this is an important treatment development for patients," said Mark Nelson, M.D., HIV Service Director, Deputy Director of HIV Research, and Lead Clinician for HIV inpatients at Chelsea and Westminster Hospital, London, United Kingdom.

The approval is based on 48-week analyses of plasma HIV RNA levels and CD4+ cell counts from ARTEMIS, an open label phase III trial in antiretroviral treatment-naïve HIV-1-infected adults. ARTEMIS studied the efficacy and safety of darunavir/r vs. lopinavir/r in combination with other antiretrovirals. The data showed that darunavir was non-inferior to the comparator: more patients in the darunavir/r arm achieved undetectable viral load (less than 50 copies/mL) compared to lopinavir/r (84 percent vs. 78 percent). The common adverse drug reactions (ADRs) reported of at least moderate intensity (\geq Grade 2) in the darunavir/r arm were hypertriglyceridaemia, hypercholesterolaemia, headache, diarrhoea, nausea, and increased alanine aminotransferase.

Darunavir 400 mg, co-administered with low dose ritonavir is indicated in combination with other antiretroviral (ARV) medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in antiretroviral therapy (ART) naïve adults.

Darunavir was given conditional marketing authorisation by the European Commission in February 2007, and received full marketing authorisation in December 2008.

"We strive to provide innovative treatment options for people living with HIV," said Roger Pomerantz, M.D., President of Tibotec Research and Development. "We are proud to make darunavir available to those who are just starting HIV treatment for the first time."

Dosing

Recommended dosing for treatment-naïve adult patients is 800 mg (two 400 mg tablets) taken with 100 mg ritonavir once daily. For treatment-experienced adult patients, the dosing for darunavir remains 600 mg taken with 100 mg ritonavir twice daily. Darunavir must be taken with food and in combination with other ARVs. Darunavir is not recommended for use in patients with severe hepatic impairment.

ARTEMIS

The submission included 48-week findings from ARTEMIS (**AntiRetroviral Therapy with TMC114 Examined In naïve Subjects**), an ongoing phase III, randomised, controlled, open-label study comparing the efficacy and safety of darunavir/r with lopinavir/r in treatment-naïve HIV-1-infected adult patients. Patients with HIV-1 viral load \geq 5,000 copies/mL were randomised to receive a darunavir/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 darunavir/r arm experienced virological failure vs. 10 percent of patients in the lopinavir/r arm.

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

- Eighty-four percent of patients in the darunavir/r arm (n=343) reached an undetectable viral load (<50 copies/mL) vs. 78 percent of patients in the lopinavir/r arm (n=346)
- The median change in CD4+ cell count from baseline was similar between darunavir/r and lopinavir/r arms (137 cells per

cubic millimeter vs. 141 cells per cubic millimeter).

About PREZISTA

PREZISTA was developed by Tibotec Pharmaceuticals. Tibotec, a division of Janssen-Cilag, will commercialise the product in Europe, Russia, Switzerland and other countries. The marketing authorisation holder for PREZISTA in Europe is Janssen-Cilag International NV.

Important Safety Information

In the registrational studies, darunavir was generally well tolerated versus the investigator selected PIs. The majority of the adverse reactions reported in patients who initiated therapy with darunavir 600 mg co-administered with 100 mg ritonavir twice daily were mild to moderate in severity. Thirty percent of the patients experienced at least one adverse drug reaction (at least grade 2 in severity and considered by the investigator at least possibly related to darunavir co-administered with 100 mg ritonavir). The most frequently (greater than or equal to 2 percent) of those reported adverse reactions were diarrhoea (3.9 percent), hypertriglyceridaemia (3.8 percent), rash (2.8 percent), nausea (2.6 percent), hypercholesterolaemia (2.5 percent) and headache (2.0 percent). 2.6 percent of the patients discontinued treatment due to adverse reactions.

Before taking darunavir, patients should tell their doctor if they have any medical conditions, including liver problems, including hepatitis B or C, diabetes, symptoms of infections, change in body fat, haemophilia, musculoskeletal problems, or allergy to sulfa medicines and should tell their doctor if they are pregnant or planning to become pregnant, or are nursing.

Darunavir should not be used in patients allergic (hypersensitive) to darunavir or ritonavir or with severe liver problems.

Due to potential drug interactions, patients should talk to their healthcare provider about all the medicines they are taking or plan to take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Darunavir does not cure HIV infection or AIDS, and does not prevent passing HIV to others. Please see full Summary of Product Characteristics for more details.

About Tibotec Pharmaceuticals

Tibotec Pharmaceuticals, based in Cork, Ireland, is a pharmaceutical research and development company, with offices in Yardley, PA, USA and its main research and development operations in Mechelen, Belgium. 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, a division of Janssen-Cilag

Tibotec, a division of Janssen-Cilag, brings innovative products for HIV/AIDS to patients in Europe, the Middle East and Africa focusing on patients' and healthcare providers' specific needs in this disease domain. The company will also commercialise medicines to combat other viral diseases in the future.

About Janssen-Cilag

Janssen-Cilag is a leader in traditional and biological medicines for disorders such as gastroenterology, women's health, mental health and neurology as well as for pain, oncology, haematology and nephrology.

Tibotec Pharmaceuticals and Janssen-Cilag are subsidiaries of the Johnson & Johnson family of companies.

(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 the Company'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 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.)

EDITORS NOTE: KEY REGULATORY TERMS

Conditional marketing authorisation: A conditional marketing authorisation can be granted subject to certain specific obligations to be reviewed annually. This is granted when a drug's benefits outweigh its risks, while additional safety and efficacy data is needed before full authorisation can be granted.

- Darunavir received conditional approval in Europe on 12 February 2007 for the treatment of highly pre-treated adult patients with HIV-1 who had failed more than one regimen containing a protease inhibitor.

Extension of indication: Extension of indications can be submitted as a variation for the use of a drug beyond its original indication.

- Darunavir was approved in Europe on 25 November 2008 for the treatment of HIV-1 infection in all treatment-experienced adult patients, including those that have been highly pre-treated.

Full approval ('marketing authorisation not subject to specific obligations'): When all specific obligations have been fulfilled, the CHMP may adopt an opinion and recommend the granting of a 'marketing authorisation not subject to specific obligations.'

- Darunavir received full approval in Europe on 16 December 2008.

MEDIA CONTACT:

Hans Vanavermaete

+32 (0) 15 461 017 (office)

+32 (0) 478 44 72 78 (mobile)