

MEDIA RELEASE

30 June 2009

Tibotec's INTELENCE[®] (etravirine) PBS listed for HIV combination therapy

First NNRTI to show efficacy in patients with NNRTI-resistant virus

INTELENCE[®] (etravirine), a new non-nucleoside reverse transcriptase inhibitor (NNRTI), and the first to show efficacy in patients with NNRTI-resistant HIV, will be available on the PBS from 1 July 2009 for HIV combination therapy.

INTELENCE[®] is indicated for the treatment, in combination with other antiretroviral agents, of HIV infection in an antiretroviral experienced patient with evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or CD4 cell counts of less than 500 per cubic millimetre.

A patient must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens which have included at least 1 NNRTI; and at least 1 nucleoside reverse transcriptase inhibitor; and at least 1 protease inhibitor.

INTELENCE[®] will be PBS listed section 100 Authority required.

As HIV patients live longer, there is a growing demand for new medicines to combat viral resistance. In addition, new medicines with improved tolerability profiles are essential to assist PLWHA sustain long term adherence to medication and halt the progression of HIV/AIDS.

INTELENCE[®] is the first new NNRTI to be introduced in approximately 10 years.

"NNRTIs have been trusted by clinicians and used in antiretroviral therapy for more than a decade, but NNRTI resistance has limited the use of this important class of HIV medication," said Dr Jonathan Anderson, a HIV doctor and member of Tibotec's Advisory Board.

"INTELENCE[®] extends the NNRTI class to treatment-experienced patients in Australia who have NNRTI-resistant virus, providing them with the potential to suppress their virus to undetectable levels and maintain their health - the ultimate treatment goal," he said.



The registration trials for INTELENCE[®] show that the addition of INTELENCE[®] to an optimized background regimen that included PREZISTA[®] (darunavir) resulted in a significant number of patients reaching undetectable viral loads. INTELENCE[®] was generally safe and well tolerated. Rash, generally mild to moderate, occurred more frequently with INTELENCE[®] compared to placebo (9 percent vs. 3.1 percent).^{1-2 -3}

The recommended oral dose of INTELENCE[®] tablets is 200 mg (two 100 mg tablets) twice daily following a meal.

“We congratulate the Government and the Department of Health and Ageing for ensuring continued access to new medications for HIV patients with limited treatment options,” said Mr. Bruce Goodwin, Janssen-Cilag Australia Managing Director.

From 1 July, INTELENCE[®] will be available only through your hospital or sexual health clinic pharmacies. Janssen-Cilag has been very pleased to be able to provide INTELENCE to nearly 400 patients Via Early Access and Compassionate Supply Programs.

“INTELENCE[®] is an important new drug for treatment-experienced patients with limited options, and the HIV community is very pleased that it will now be available to patients on the PBS,” said John Daye, Co-convenor of NAPWA’s Health, Treatments and Research Portfolio.

“Tibotec has shown a true commitment to working with the community to make INTELENCE[®] available to patients in need”, he said.

INTELENCE[®] was developed by Tibotec Pharmaceuticals, Ltd., and will be marketed in Australia by the Tibotec division of Janssen Cilag Pty Ltd, part of the Johnson & Johnson Family of Companies.

¹ Madruga, JV., et al., *Efficacy and safety of TMC125 (etravirine) in treatment-experienced HIV-1 infected patients in DUET-1: 24-week results from a randomised, double-blind, placebo-controlled trial.* Lancet, 2007. 370: 29-38.

² Lazzarin, A., et al., *Efficacy and safety of TMC125 (etravirine) in treatment-experienced HIV-1 infected patients in DUET-2: 24- week results from a randomised, double-blind, placebo-controlled trial.* Lancet, 2007. 370: 39-48.

³ Janssen-Cilag Pty Ltd, *Australian Approved Product Information (Intelence[®] -etravirine).* Therapeutic Goods Administration approval of last amendment 4 December 2008. INTELENCE is a registered trademark of TIBOTEC PHARM for etravirine tablets.

PBS Information: Section 100.
Private Hospital Authority Required.
Refer to PBS Schedule for full information.

ENDS

For further information, please contact Adam Roach (0408 240 149) at Janssen-Cilag Australia.

Background Information

About NNRTIs

Non-nucleoside reverse transcriptase inhibitors (NNRTIs) work by blocking 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. Generally, when patients develop resistance to one NNRTI, they are resistant to all first-generation drugs in the class. INTELENCE[®] is the first NNRTI to show efficacy in patients with NNRTI-resistant virus.

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, USA. Tibotec is dedicated to the discovery and development of innovative HIV/AIDS drugs and anti-infectives for diseases of high unmet medical need.

Janssen-Cilag Australia Pty Ltd

Janssen-Cilag Australia Pty Ltd is a leader in traditional and biological medicines for disorders in virology, mental health and neurology, gastroenterology as well as for pain, oncology, haematology and nephrology.