

Australian first in HIV Treatment to commence on 1 January

–HIV specialists recognise the need for simplified treatments which reduce the number of tablets required for people living with HIV, while maintaining safety and efficacy¹ –

Embargo: Thursday 17 December 2009

At midnight on 31 December, Australians celebrating the New Year will also be seeing in an Australian-first. For the first time Australians living with HIV will be able to access a medicine which combines three HIV treatments into a single once-daily tablet, for the cost of a single PBS script.

From 1 January 2010 ATRIPLA[®] (tenofovir disoproxil fumarate 300 mg/ emtricitabine 200mg/ efavirenz 600 mg) will be available on the Pharmaceutical Benefits Scheme (PBS) for the treatment of HIV infection in adults.² This will be for those who are either starting their first treatment, or changing from other HIV treatments.

The announcement comes at a time when new Australian epidemiological research shows that despite some advances in the lives of people living with HIV, there is a concerning trend when it comes to the proportion of people living below the poverty line.³

“Australians have a lot to be proud of in our response to HIV,” said Professor David Cooper, AO FAA, Director of the National Centre in HIV Epidemiology and Clinical Research (NCHECR), University of NSW. “One of Australia’s greatest achievements was minimising the spread of HIV in the early days of the epidemic, meaning Australia now has one of the lowest rates of HIV infection worldwide. However, we still need new medications which work to stop the virus from multiplying, helping people living with HIV lead healthier lives.”

HIV specialists have long agreed on the need for simplified medicines in HIV.^{1,4,5} Current Australian and international treatment guidelines recommend treating HIV with a combination of at least three drugs, referred to as highly active antiretroviral therapy treatment (HAART).⁶ However, in the past treating HIV has been a challenge for many patients as the treatments combined complicated medication schedules (incl. the need for multiple tablets taken daily) leading to some people not taking their treatments as prescribed.⁴

Approximately 17,500 Australians are currently living with HIV,^{7,8} with around 60 percent⁹ taking antiretroviral therapy.

“Clinical studies show that helping people with HIV to take their medication as prescribed is important in optimising treatment outcomes and minimising the emergence of HIV drug resistance,” said Prof Cooper. “Thus medications like ATRIPLA which combine three clinically proven and well established anti-HIV medicines in a single once daily tablet represents an important step forward in dosing simplification.”

“People with HIV are looking for treatments which are proven to control their HIV infection and enable them to get on with the rest of their lives,” said Mr Peter Canavan, Senior Coordinator, Health Treatments & Research Unit of the National Association of People Living with HIV/AIDS (NAPWA). “Thus new medications like ATRIPLA which are designed to lower the number of tablets needed by people with HIV are very welcome.”

Australians living with HIV who are able to switch to ATRIPLA can simplify their treatment and maintain effective control of their infection.¹⁰ The once daily single tablet contains three medicines from two classes of anti-HIV drugs. ATRIPLA contains 300 mg of tenofovir disoproxil fumarate (Viread[®]), 200 mg of emtricitabine (Emtriva[®]), a nucleotide and nucleoside reverse transcriptase inhibitor (NRTIs) and 600 mg of efavirenz (Stocrin[®]), a non-nucleoside reverse transcriptase inhibitor (NNRTI).⁹ (Truvada[®] also contains tenofovir disoproxil fumarate and emtricitabine). All three active ingredients work by blocking reverse transcriptase, an enzyme needed for the HIV virus to multiply.

“Controlling levels of the virus is the number one priority in HIV treatment, which is why multiple antiretroviral drugs are often required,” said Prof Cooper. “The challenge facing healthcare professionals and the pharmaceutical industry is how to make these treatments as easy to take as possible.”

For Australians who are currently on multiple HIV medications, simplifying their treatment to ATRIPLA should also save money. From 1 January 2010 people living with HIV who are eligible for treatment with ATRIPLA will be able to access it for the cost of a single PBS script² (\$32.90 for general patients or \$5.30 for concession card holders), which is an important monthly saving for those who were previously taking multiple medications.

“Cost is an important issue for a significant number of Australians living with HIV. Research just released by The Australian Research Centre in Sex, Health and Society found that just under half of all survey respondents living with HIV receive a government pension or benefit as their main source of income and many have difficulties meeting their everyday living costs, hence reducing the cost of medication is an excellent step,” said Mr Canavan.

Australian data released this month shows that there have been many advances for people living with HIV, such as the number of people now on antiretroviral drugs.^{3,8} However, there are still areas for significant improvement – in only three years the number of Australians with HIV living below the poverty line has increased by 10 percent, despite the fact that more people living with the condition are now in paid employment.^{3,8}

“ATRIPLA is supported by Australian and international guidelines for HIV management,” said Prof Cooper. “This new PBS funding serves as a timely reminder to the wider community that despite our early successes, HIV remains an important issue in Australia, with diagnosis rates increasing by a third over the past decade.”

– ENDS –

PBS information prior to the new PBS listing on 1 January 2010:

PBS Information: ATRIPLA is not yet PBS listed for treatment of HIV.

For full Consumer Medicine Information please visit:

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2009-CMI-01079-3>

Minimum Product Information – ATRIPLA

ATRIPLA (300 mg tenofovir disoproxil fumarate/200 mg emtricitabine/600 mg efavirenz) tablets. INDICATIONS: HIV infection in adults (>18 years). **DOSAGE AND ADMINISTRATION:** One tablet, daily, orally on an empty stomach at bedtime. Dosing adjustment required in moderate or severe renal impairment (creatinine clearance <50 mL/min) and cannot be achieved with ATRIPLA; individual agents are available. **CONTRAINDICATIONS:** Hypersensitivity to active substances or excipients. Concurrent use: terfenadine, astemizole, cisapride, midazolam, triazolam, bepridil, pimozone, ergot derivatives, voriconazole. **PRECAUTIONS:** Concurrent use with other drugs containing tenofovir DF, emtricitabine,

efavirenz, lamivudine, adefovir dipivoxil. Lactic Acidosis/Severe Hepatomegaly with Steatosis. Renal Impairment (calculate CrCl). Bone Effects. Hepatic Impairment. Post treatment exacerbations of hepatitis in co-infected patients (HIV/HBV). Psychiatric Symptoms. Nervous System Symptoms (generally resolve after 2-4 weeks). Convulsions (patients with history of seizures). Skin Rash. Lipodystrophy. Immune Reconstitution Syndrome. Monitoring virological failure and/or emergence of resistance. Children. Pregnancy (category D) and lactation. Effects on ability to drive and use machines. **DRUG INTERACTIONS:** Not recommended with atazanavir, atazanavir/ritonavir, drugs that decrease or compete for renal clearance or compete with active tubular secretion, nephrotoxic agents, St. John's wort or St. John's wort-containing products. Dosage adjustments may be required: lopinavir/ritonavir, rifampicin, diltiazem, drugs that induce CYP3A4 activity, methadone (monitor withdrawal signs). Potential drug interactions to take into consideration: amprenavir, fosamprenavir calcium, ritonavir (monitor liver enzymes), saquinavir (do not use as sole protease inhibitor), didanosine (closely monitor for didanosine-associated adverse events), clarithromycin, rifabutin, itraconazole, anticonvulsants (periodic monitoring of plasma levels), sertraline, oral contraceptives (barrier contraception should also be used), cannabinoid test interaction. **ADVERSE EFFECTS:** *tenofovir DF* - nausea, diarrhoea, vomiting, flatulence, dizziness, increased creatinine, renal failure, Fanconi syndrome. *emtricitabine* - headache, diarrhoea, nausea, rash (including skin discolouration), increased liver enzymes (AST, ALT), hyperbilirubinaemia, increased creatine kinase, hypertriglyceridaemia, neutropaenia, increased amylase (including pancreatic), hyperglycaemia, increased serum lipase, anaemia. *efavirenz* - rash, dizziness, nausea, headache, fatigue, paranoid reaction, suicide, psychosis, delusion, convulsions, cerebellar coordination and balance disturbances, blurred vision, pancreatitis, hepatic failure, impaired concentration, insomnia, anxiety, abnormal dreams/thinking, depression, hallucination. **This is not a full list for more details/complete list of adverse events refer to full Product Information. Full Product Information is available from Gilead Sciences Pty Ltd and should be reviewed before prescribing ATRIPLA.** Date of Preparation: 12 November 2009

Editor's notes:

About HIV: please refer to separate factsheet.

About the PBS listing:² From 1 January 2010 ATRIPLA[®] is available on the PBS [Section 100 (Highly Specialised Drugs Program); Private hospital authority required] for:

Treatment of HIV infection in patients with: a) CD4 cell counts of less than 500 per cubic millimetre; b) viral load of greater than 10,000 copies per mL

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References:

1. The DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents - A Working Group of the Office of AIDS Research Advisory Council (OARAC). *Guidelines for the use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*. Australia: November 3, 2008
2. Data on file – Gilead Sciences. Correspondence from Pharmaceutical Evaluation Branch. 1 December 2009
3. Australian Research Centre in Sex, Health and Society. *HIV Futures Six: Making Positive Lives Count* (Summary). Melbourne: LaTrobe University. December 2009
4. DeJesus E, Young B, Morales-Ramirez JO *et al*. Simplification of antiretroviral therapy to a single-tablet regimen consisting of efavirenz, emtricitabine, and tenofovir disoproxil fumarate versus unmodified antiretroviral therapy in virologically suppressed HIV-1-infected patients. *J Acquir Immune Defic Syndr* 2009 Jun 1;**51**(2):163-74
5. Stone VE, Jordan J, Tolson J *et al*. Perspectives on adherence and simplicity for HIV-infected patients on antiretroviral therapy: self-report of the relative importance of multiple attributes of highly active antiretroviral therapy (HAART) regimens in predicting adherence *J Acquir Immune Defic Syndr* 2004;**36**:808-816
6. Australian Federation of AIDS Organisations. *HIV tests and treatments*. 2009
7. National Centre in HIV Epidemiology and Clinical Research. Australian Annual Surveillance Report 2009
8. Grierson J, Thorpe R, Pitts M. *HIV Futures Five: Life as we know it*. Melbourne: LaTrobe University. October 2006
9. The Australian HIV Observational Database. *Annual Report* October 2009; 9(1):14
10. Gilead Sciences. *ATRIPLA Consumer Medicine Information*. 8 October 2009