

New 'Superbug' Antibiotic Approved for Use in Australia

MELBOURNE, Australia - April 26, 2013 - An effective new antibiotic designed to specifically treat the common superbug* infection *Clostridium difficile*-associated diarrhoea will be available to patients in Australia from 14th May 2013.

Melbourne biopharmaceutical company Specialised Therapeutics Australia Pty Ltd (STA) has received Therapeutic Goods Administration (TGA) approval to market the drug DIFICID (fidaxomicin) in Australia. Until now, it has only been available in Australia under the Special Access Scheme.

DIFICID is indicated for the treatment of confirmed *Clostridium difficile* (CDI) infections in adults.¹

The macrocyclic antibiotic therapy, taken in tablet form, is regarded as a breakthrough treatment to help fight serious CDI, which typically develops in patients following broad-spectrum antibiotic use. CDI targets the large intestine, causing diarrhoea which can range from moderate & debilitating to severe & life-threatening. It is extremely common in hospitals and aged care facilities as older patients are particularly vulnerable, and can be fatal.²

A recent media report indicated 14 Victorians died from the infection during a 15-month period in 2010 and 2011.³ According to data generated by the Quebec provincial hospitalisation database, there were 7004 cases of *C. difficile* across Quebec from April 1st 2003 to March 31st 2004, and 1270 people died after contracting CDI.⁴

Medical experts say Australian infection rates have at least doubled in recent years in major public hospitals, but concede the incidence of CDI is under reported.

STA Chief Executive Officer Mr Carlo Montagner is excited about the valuable treatment alternative DIFICID offers Australian patients who contract CDI.

“DIFICID is a potentially life saving drug for this extremely serious infection plaguing public hospitals and the wider community,” he said. “Unfortunately, it is estimated that almost 30% of patients can have a recurring infection. DIFICID is the only approved drug on the market which studies have shown will lower the risk of that infection returning.”

DIFICID is the first in a new class of antibiotics which are minimally absorbed by the bloodstream and have been shown to fight CDI while leaving healthy gut flora untouched.⁵

Hypervirulent strains of *C. difficile*, including the PCR ribotype 027 strain recently identified in Australia, have been associated with epidemic spread and high rates of severe disease and death.⁶

Risk factors for CDI include exposure to antimicrobial drugs, gastric acid-suppressive therapy, advanced age, prolonged hospitalisation, cancer chemotherapy, co-morbidity and immuno-suppression. Although most cases have been in hospital inpatients, increasing numbers of community-associated cases are now being reported.²

Leading Australian CDI expert Professor Thomas Riley from The University of Western Australia, acknowledged that studies had demonstrated patients treated with DIFICID were significantly less likely to develop recurrent infections.^{7,8}

He regarded DIFICID as an important new treatment alternative, with infection rates of *C. difficile* climbing substantially in public hospitals around the country.

“Introducing DIFICID to Australia basically means we have another drug in the arsenal to treat this infection. Until now, we have had only two drugs available.

“Fewer recurrences will help contain the spread of the illness. Most importantly, DIFICID will benefit individual patients, who become weaker and more vulnerable with each recurrent infection, enormously.”

STA licenses DIFICID for the Australian market from US-based Optimer Pharmaceuticals. Optimer Chief Executive Officer & Chairman of the Board, Dr Henry McKinnell, said he was confident DIFICID would provide a valuable new treatment option for an unmet medical need in Australia. “With the recent

approval in Australia, fidaxomicin is now approved by four regulatory agencies, broadening access to patients in need across the globe,” said Dr. Henry McKinnell. “CDI infections represent a global healthcare challenge, and we believe an innovative drug like DIFICID that can deliver a substantial clinical improvement over existing therapies is an important new option that should be widely available to patients.”

About DIFICID[®]

Fidaxomicin is a novel antibiotic agent and the first of a new class of antibacterials called macrocycles. Fidaxomicin is bactericidal against *C difficile* in vitro, inhibiting RNA synthesis by RNA polymerases.¹

DIFICID was studied for the treatment of CDI in two randomised Phase III studies and was found to have equivalent efficacy to vancomycin. Notably, DIFICID was associated with significantly greater improvements in the rate of sustained clinical response and significantly lower rates of CDI recurrence (than vancomycin).^{1,7,8}

Contraindications and side effects:¹

Like all medications, DIFICID may cause side effects. DIFICID should not be used in patients who are hypersensitive to any ingredient in the formulation or component of the container. As there is minimal systemic absorption of DIFICID, it should not be used for the treatment of systemic infections. Most common side effects ($\geq 1/10$) caused by DIFICID include nausea, constipation and vomiting.

For further information regarding DIFICID and potential side effects, physicians should review the DIFICID Approved Product Information available from www.specialisedtherapeutics.com.au/index.php?q=clinician-resources.html and patients should consult their prescribing physician or the DIFICID Consumer Medicine Information available in the pack or via www.specialisedtherapeutics.com.au/index.php?q=dificid.html

About CDI

CDI has become a significant medical problem in hospitals, long-term care facilities and the community. CDI is a serious illness resulting from infection of the inner lining of the colon by *C. difficile*, which produces toxins that cause inflammation of the colon, severe diarrhoea and, in the most serious cases, death. Patients typically develop CDI following the use of broad-spectrum antibiotics which disrupt normal gastrointestinal (gut) flora, possibly allowing *C. difficile* to enter the gut and flourish. Older patients in particular are at risk for CDI, potentially because of a weakened immune system or the presence of underlying disease. Approximately two-thirds of CDI patients are 65 years of age or older. Historically, approximately 20 - 30% of CDI patients who initially respond to treatment experience a clinical recurrence.⁷

About Specialised Therapeutics Australia

Specialised Therapeutics Australia Pty Ltd (STA) is a biopharmaceutical company dedicated to working with leading pharmaceutical companies worldwide to provide acute care therapies for high unmet medical needs to people living in Australia and New Zealand. The STA therapeutic portfolio and pipeline at present encompasses oncology and infectious diseases. STA also has interests in the therapeutic areas of respiratory, dermatology, endocrinology and central nervous system (CNS). Additional information can be found at www.specialisedtherapeutics.com.au

About Optimer Pharmaceuticals

Optimer Pharmaceuticals, Inc. is a global biopharmaceutical company focused on developing and commercialising innovative hospital specialty products that have a positive impact on society. Optimer developed DIFICID (fidaxomicin) tablets, an FDA-approved macrolide antibacterial drug for the treatment of *Clostridium*

difficile-associated diarrhoea (CDAD) in adults 18 years of age and older and is commercializing DIFICID in the US and Canada. Optimer also received marketing authorisation for fidaxomicin tablets in the European Union, where its partner, Astellas Pharma Europe, is commercialising fidaxomicin under the trade name DIFICLIR™. The company is exploring marketing authorisation in other parts of the world where *C. difficile* has emerged as a serious health problem. Additional information can be found at www.optimerpharma.com.

OPTIMER and DIFICID are trademarks of Optimer Pharmaceuticals, Inc. All other trademarks are the property of their respective owners.

* Superbug is a common term to describe a bacterium that is resistant to multiple antibiotics.

References:

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