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Singapore: A new therapy to treat a common hospital superbug infection Clostridium difficile will soon be available to Australian and New Zealand patients.

Melbourne biopharmaceutical company Specialised Therapeutics Australia (STA) has entered into an exclusive distribution and license agreement with US-based Optimer Pharmaceuticals to develop and commercialize the drug DIFICID in Australia and New Zealand.

This macrolide antibiotic therapy, taken in tablet form, is regarded as a breakthrough treatment to help fight the serious CDI, which typically develops in patients using broad-spectrum antibiotics. The organism - which is resistant to many common household and commercial disinfecting agents - targets the large intestine, causing diarrhoea. It is extremely common in hospitals and aged care facilities and can be fatal.

A recent media report indicated 14 people in Victoria, Australia, died from the infection during a 15-month period in 2010 and 2011. According to data generated by the Quebec provincial hospitalization 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.

STA chief executive officer Mr Carlo Montagner said, "CDI presents a serious bacterial health threat and current CDI treatment options available in Australia and New Zealand are limited. Our license of DIFICID provides a great opportunity to bring a much-needed new therapy to patients."

DIFICID is the first in a new class of macrolide antibiotics, which are minimally absorbed by the bloodstream and have been shown to fight the CDI infection while leaving healthy gut flora untouched.4 DIFICID works by inhibiting the bacterial enzyme

RNA polymerase, resulting in the death of C. difficile bacteria.4 Patients typically develop CDI when using broad spectrum antibiotics, which disrupt normal gut flora and enable the infection to take hold.

Hypervirulent strains of CDI, including PCR ribotype 027 strains recently identified in Australia, have been associated with epidemic spread and high rates of severe disease and death.5

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.

A leading Australian authority on C. difficile, Professor Thomas Riley from the University of Western Australia, said data showed patients treated with DIFICID were "significantly less likely" to develop recurrent infections.6,7

He said new treatment options like DIFICID were highly desirable, with infection rates rising "two to three fold" in public hospitals around the country.

An application to make DIFICID widely available in Australia has been filed with the Therapeutic Goods Administration, with the drug expected to be launched by June 2013.
Optimer Chief Executive Officer Pedro Lichtinger said he looked forward to DIFICID being widely available in Australia and New Zealand. "We are committed to enabling better outcomes for patients with this difficult to treat infection. I believe this is a truly innovative therapy providing a new patient option for an unmet medical need," he said.

DIFICID is approved by the US Food and Drug Administration for the treatment of Clostridium difficile-associated diarrhoea (CDAD) in adults 18 years of age or older. Likewise, the European Commission granted Marketing Authorisation to fidaxomicin for the treatment of adults with Clostridium difficile infections under the trade name DIFICLIR.