

Positive Data on RECCE[®] 327 Against *Neisseria gonorrhoeae* in STD Animal Model

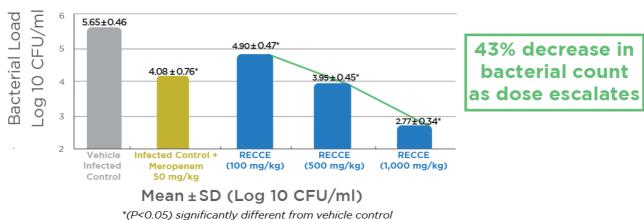
Highlights:

- Statistically significant reduction of *Neisseria gonorrhoeae* bacteria in reproductive organs of female mice
- RECCE[®] 327 outperformed market approved drug Meropenem in most instances

Sydney Australia, 4 May 2020: Recce Pharmaceuticals Ltd (**ASX: RCE**) (**Company**), the Company developing a New Class of Broad-Spectrum Synthetic antibiotics, today announced positive efficacy showing significant antibacterial activity against *Neisseria gonorrhoeae* bacteria in mice treated with its lead compound RECCE[®] 327.

The study was conducted by an independent Contract Research Organisation to assess the dose-dependency of RECCE[®] 327 and in-vivo antibacterial activity against *Neisseria gonorrhoeae* (*N. gonorrhoeae*), a species of Gram-negative bacteria, and the second most common sexually transmitted infection (STI) globally.¹ The recognised vaginal infection model met its primary endpoint of a reduction in bacterial load compared to vehicle infected control evaluated on the seventh day following dosing.

Three groups of 10 female mice each showed RECCE[®] 327 efficacy at different dose levels with significant reduction in bacterial load in the vaginal infection as compared to the vehicle control (p<0.05).



Efficacy of RECCE°327 Against Neisseria Gonorrhoeae in Mice

¹ NCBI, National Institute of Health



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	Log10 CFU/Swab (Mean ± SD)(n=8)	
Group	Treatment Group***	Day 9 PI**
1	Vehicle infected control	5.65 ± 0.46
2	Infected control + Marketed Drug [50mg] Meropenem	4.08 ± 0.76*
3	Infected + RECCE [®] 327 (100 mg/kg)	4.90 ± 0.47*
4	Infected + RECCE [®] 327 (500 mg/kg)	3.95 ± 0.45*
5	Infected + RECCE [®] 327 (1000 mg/kg)	2.77 ± 0.34*

CFU: colony-forming units- Used to estimate number of bacteria in a sample.

*(P<0.05) significantly different from vehicle control;

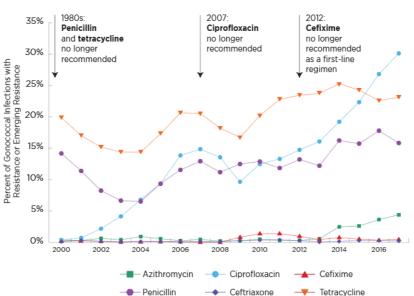
** PI – Post Infection

*** Treatment began two days post infection and received IV bolus twice daily duration of treatment - seven days

The study director concluded, "RECCE[®] 327 showed significant dose dependent antibacterial effect in vaginal load at 100, 500 and 1000 mg/kg given by intravenous (IV) bolus when compared to the control group seven days post infection."

In this study Meropenem, a broad spectrum carbapenem antibiotic, was used at its optimum dose as the recognised efficacy model. In practice however, Meropenem's high rates of bacterial resistance have recently led to restriction of its use strictly reserved for infections caused by resistant organisms.²

EMERGING ANTIBIOTIC RESISTANCE



Gonorrhea rapidly develops resistance to antibiotics—ceftriaxone is the last recommended treatment.

The World Health Organisation (WHO) lists N. gonorrhoeae as a priority pathogen on its list of

² Ohio State Publications

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recce.com.au ACN 124 849 065 antibiotic-resistant bacteria that pose the greatest threat to human health.³ The leading national public health institute of the U.S., the Centers for Disease Control and Prevention (CDC) estimates drug-resistant *N. gonorrhoeae* results in 550,000 infections each year, with a total of 1.14 million infections from *N. gonorrhoeae* annually.⁴

Dr John Prendergast, Recce Pharmaceuticals Non-Executive Chairman said, "Gonorrhea has developed resistance to all but one class of antibiotics, so there is an urgent need to find a new class of effective antibiotics to kill the pathogen, before it develops resistance to the last recommended treatment. Data from this study, along with previous other reports, continue to highlight the potential of RECCE[®] 327 to not only become a potent broad spectrum antibiotic but most critically to continue working against antibiotic resistant bacteria or superbugs, even with numerous repeated uses."

This announcement has been approved for release by Recce Pharmaceuticals Board.

³ WHO list of bacteria

⁴ CDC Drug Resistance Threats

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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE) is pioneering the development and commercialisation of a New Class of Synthetic Antibiotics with Broad Spectrum activity designed to address the urgent global health problem of antibiotic resistant superbugs.

Recce antibiotics are unique – their potency does not diminish even with repeated use, which is a common failure associated with existing antibiotic use and the resulting emergence of resistant superbugs.

Patented lead candidate RECCE^{\otimes} 327, wholly owned and manufactured in Australia, has been developed for the treatment of blood infections and sepsis derived from *E. coli* and *S. aureus* bacteria – including their superbug forms.

The FDA has awarded RECCE[®] 327 *Qualified Infectious Disease Product* designation under the *Generating Antibiotic Initiatives Now* (GAIN) Act – labelling it for Fast Track Designation, plus 10 years of market exclusivity post approval.

Recce wholly owns its automated manufacturing, ready to support first-in-human clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of RECCE[®] technologies targeting synergistic, unmet medical needs.



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