ASX Announcement

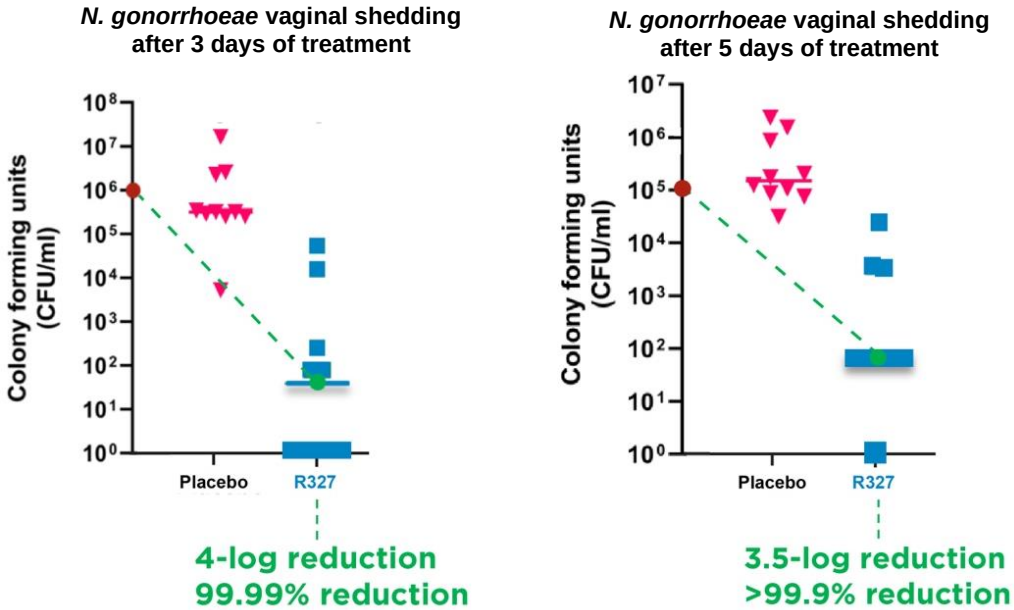
Positive Data from Murdoch Children's Research Institute Against *Neisseria gonorrhoeae* in Animal Model

Highlights:

- **RECCE® 327 again demonstrates significant bactericidal activity against deadly *Neisseria gonorrhoeae* (*N. gonorrhoeae*) pathogen – 4-log (99.99%) and 3.5-log (>99.9%) reduction**
- **Previous independently conducted study on *N. gonorrhoeae* supports results received from Murdoch Children's Research Institute**
- ***N. gonorrhoeae* listed as a priority pathogen on World Health Organisation's list of bacteria that poses greatest threat to human health**

SYDNEY Australia, 14th December 2023: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**), the company developing a new class of Synthetic Anti-infectives, is pleased to announce positive efficacy of RECCE® 327 (**R327**) showing significant antibacterial activity against *Neisseria gonorrhoeae* (***N. gonorrhoeae***). The study was conducted by Murdoch Children's Research Institute to test the efficacy of R327 treatment against *N. gonorrhoeae* in a mouse vaginal infection model.

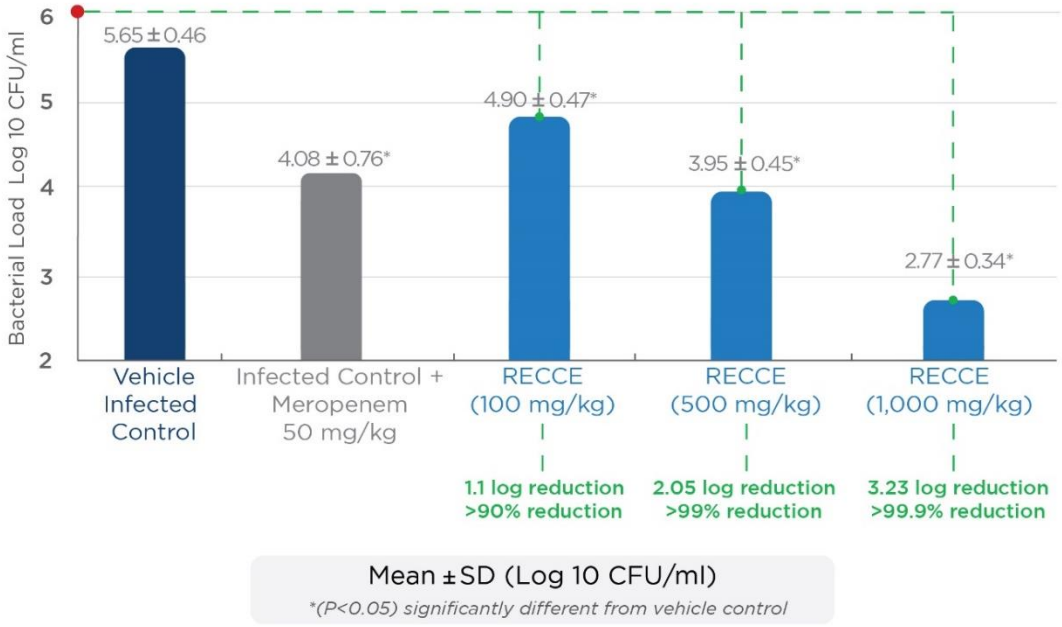
Groups of 10 mice were inoculated vaginally with *N. gonorrhoeae.* R327 was administered twice daily as IV bolus dose of 1,000mg/kg and after three days, the mice treated with R327 showed an approximate 4-log (**99.99% reduction**) reduction in bacterial shedding – significant bactericidal activity. After five days of treatment, R327 showed a 3.5-log reduction (**>99.9% reduction**) in bacterial shedding compared to the placebo-treated group.



By the end of the treatment period, R327 was successful in significantly reducing vaginal gonococcal shedding, a study where a two-log reduction – equivalent to 99% reduction in bacterial burden - is commonly considered as of significant effect. The mice in this study displayed no clinical signs of gonococcal infection.

In a previous gonorrhoea STD animal model study conducted by an independent contract research organisation, R327 showed significant dose-dependent antibacterial effect in vaginal load at 100, 500 and 1,000 mg/kg given by intravenous (I.V.) bolus for 7 days (twice daily) when compared to the vehicle infected control group seven days post-infection. 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.

Efficacy of RECCE® 327 Against *N. gonorrhoeae* in Mice



I.V. administration, as was used in these studies, further emphasises the systemic potential to treat wide-ranging bacterial infections. A late-stage preclinical study comparing I.V. administration vs a topical application (gel & spray R327) against *N. gonorrhoeae* is underway. R327 has demonstrated positive safety and tolerability in respective human clinical studies that would support if pre-clinicals are successful, to enter a Phase II study.

Antimicrobial resistance to gonorrhoea is a serious and growing problem, rendering many classes of antibiotics ineffective with the risk of becoming untreatable.[1] Current treatment involves combination therapy using at least two antibiotics (ceftriaxone and azithromycin); however, bacterial resistance has recently led to restriction for infections caused by resistant organisms.

[1] https://www.who.int/news-room/fact-sheets/detail/gonorrhoea-(neisseria-gonorrhoeae-infection)

recce.com.au
ACN 124 849 065

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

Media and Investor Relations

Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Jordyn Temperato
LifeSci Communications
jtemperato@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com

The World Health Organisation (WHO) has recognised gonorrhoea as a significant public health problem and is on the rise worldwide, with strains resistant to many antibiotics emerging. In 2020, WHO estimated 82.4 million new infections with *N. gonorrhoeae* among adults aged 15 to 49 years.

James Graham, Chief Executive Officer of Recce Pharmaceuticals Ltd said, “The need for a new class of anti-infectives could not be greater, especially against a lethal pathogen such as *N. gonorrhoeae*. The data from this study, along with the previous findings, emphasise the capability of R327 to demonstrate broad spectrum activity against antibiotic-resistant bacteria, even with repeated use.”

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

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ACN 124 849 065

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: **RCE**, FSE: **R9Q**) is developing a New Class of Synthetic Anti-Infectives designed to address the urgent global health problems of antibiotic-resistant superbugs and emerging viral pathogens.

Recce's anti-infective pipeline includes three patented, broad-spectrum, synthetic polymer anti-infectives: RECCE® 327 as an intravenous and topical therapy that is being developed for the treatment of serious and potentially life-threatening infections due to Gram-positive and Gram-negative bacteria including their superbug forms; RECCE® 435 as an orally administered therapy for bacterial infections; and RECCE® 529 for viral infections. Through their multi-layered mechanisms of action, Recce's anti-infectives have the potential to overcome the hypercellular mutation of bacteria and viruses – the challenge of all existing antibiotics to date.

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. Further to this designation, RECCE® 327 has been included on The Pew Charitable Trusts Global New Antibiotics in Development Pipeline as the world's only synthetic polymer and sepsis drug candidate in development. RECCE® 327 is not yet market approved for use in humans with further clinical testing required to fully evaluate safety and efficacy.

Recce wholly owns its automated manufacturing, which is supporting present clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of its technologies targeting synergistic, unmet medical needs.

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