ASX Announcement

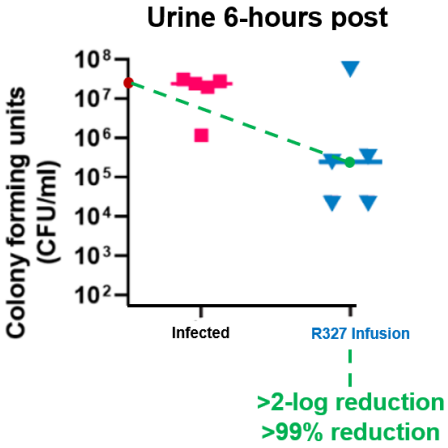
Positive Efficacy Data in Murdoch Children's Research Institute Urinary Tract Infection Animal Study

Highlights:

- **Murdoch Children's Research Institute data shows significant RECCE® 327 (R327) bactericidal activity against *Escherichia coli* Urinary Tract Infections (UTI) in rat model via intravenous infusion and new direct-to-bladder delivery**
- **R327 is currently undergoing a Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial to address needs at first patient presentation in GP and hospital settings**
- **In 2019, >404.6m individuals had UTI's globally, ~80% resistant to two or more antibiotics**
- **Results of UTI study support potential for present Phase I/II Clinical Trial**

SYDNEY Australia, 28 December 2023: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), developing a new class of Synthetic Anti-infectives, is pleased to announce further positive efficacy data, with RECCE® 327 (R327) showing significant antibacterial activity against *Escherichia coli* (*E. coli*) urinary tract infections (UTI) by Murdoch Children's Research Institute in a physiologically relevant rat UTI model.

Study 1 – Efficacy of R327 against *E. coli* UTI in a rat model

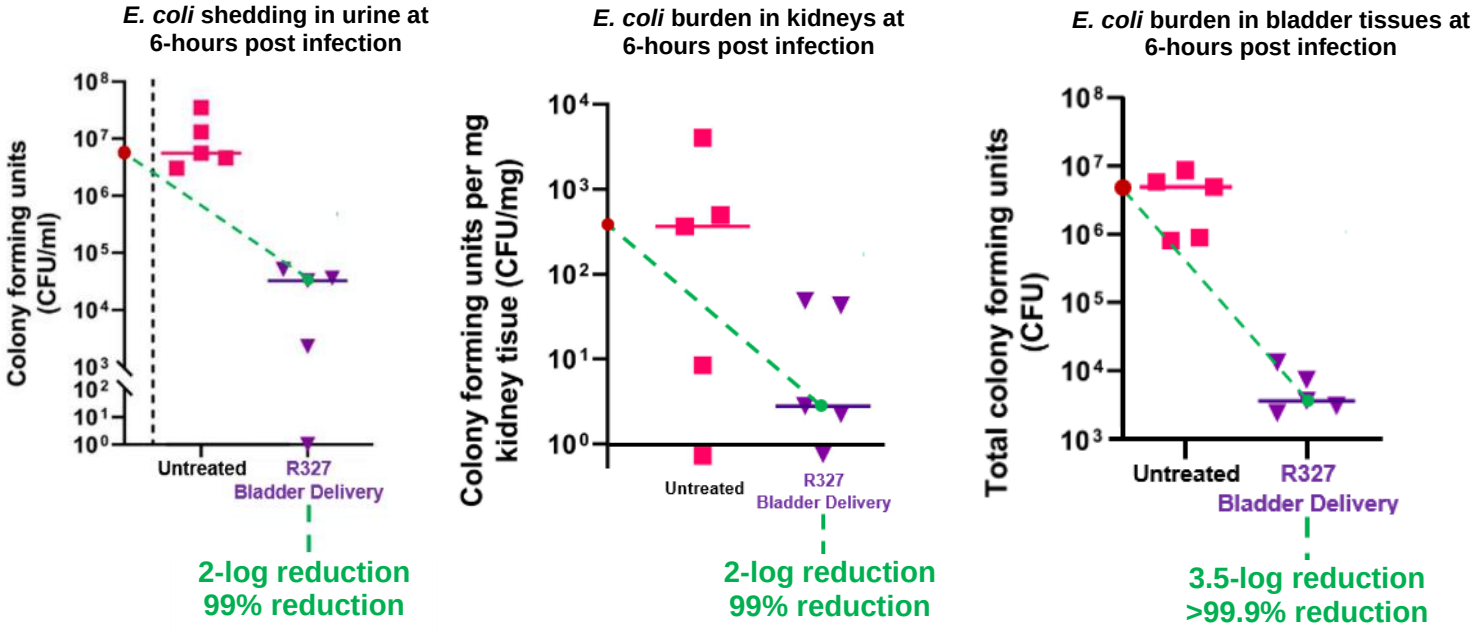


Study 1 resulted in over a >99% reduction (>2-log reduction) of *E. coli* UTI in a rat model. The study used 500 mg/kg dosing of R327 over a 1-hour infusion to test the efficacy of R327 treatment in a physiologically relevant rat UTI model. A reduction of bacterial load in urine at 6-hours post-infection (6phi) was observed.

Study 2 – Efficacy of R327 against *E. coli* UTI direct-to-bladder

Study 2 tested the efficacy of R327 against an *E. coli* UTI in a rat model-modified treatment protocol. The dose was doubled from Study 1 to 1,000 mg/kg and given twice (at 2 hours and 4 hours post-infection) for a total dose of 2,000 mg/kg, delivered via direct-to-bladder. Endpoints to assess efficacy were conducted at 6-hours post-infection.

Bacterial shedding of *E. coli* in the urine was measured, where a 2-log reduction (approx. 99% bacterial kill) for the R327 bladder delivery compared to the untreated control group. Bacterial burden of *E. coli* in kidney tissue was also analysed, with a 2-log (99% kill) reduction for R327 direct-to bladder delivery. Bacterial burden was analysed for *E. coli* in bladder tissue, with a bactericidal (>99.9% kill) 3.5-log and statistically significant reduction observed for the bladder delivery, compared to the untreated control group.



UTI's are most commonly caused by *E. coli* bacteria (Gr-) with 404.6 million individuals having UTI's globally in 2019[1] (~80% resistant to two or more antibiotics). In 2017, UTI-associated healthcare costs totalled >AU$7.56 billion annually. If undiagnosed or untreated, UTIs can progress to systemic bacteraemia infections, which can trigger sepsis and septic shock.[2]

R327 is currently undergoing a Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial to deliver the drug at faster infusion rates as a broad-spectrum anti-infective across the full spectrum of UTIs (simple, complicated and recurring) through to their all-out septic state 'Urosepsis'. The fast I.V. infusions with ex vivo testing of participants urine containing R327 to kill *E. coli* and is progressing as planned. The study further investigates R327 as a viable treatment option for first patient presentation in both early stage (GP) and late stage (hospital) settings.

Antibiotics administered as an intravenous infusion (usually over 30 minutes) provide benefits such as savings in nursing time, reduced costs and improved safety. In an outpatient setting, I.V rapid infusion of antibiotics is further useful, as the speed of medication infusion can impact the number of

[1] https://pubmed.ncbi.nlm.nih.gov/35066637/#:~:text=Results%3A%20In%202019%2C%20more%20than,(4.5%2D5.7)%20DALYs.

[2] https://www.publish.csiro.au/ma/fulltext/ma21031#:~:text=In%202018%20for%20example%2C%20E,48%20h%20after%20admission)15.

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

patients treated, patient wait times, and duration that patients are connected to infusers.[3] The 2021 Surviving Sepsis Campaign (SCC) guidelines strongly recommend that the administration of intravenous broad-spectrum antibiotics should be initiated as soon as possible, preferably within an hour of sepsis recognition.[4]

James Graham, Chief Executive Officer of Recce Pharmaceuticals Ltd said, “We are delighted to have received further UTI efficacy data from the two studies conducted at Murdoch Children's Research Institute. This instils confidence in the prospect of advancing R327 to a Phase II clinical trial for UTI/Urosepsis."

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

[3] https://www.ijidonline.com/article/S1201-9712(21)00574-9/fulltext

[4] https://pubmed.ncbi.nlm.nih.gov/34605781/

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

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.

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