

Cohort Dosing Complete

Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial

Highlights:

- **Dosing of 6 human subjects complete in Phase I/II UTI/Urosepsis fast infusion intravenous study of RECCE® 327 (R327) at 4,000mg over 20 minutes – highest dosage to date in this clinical trial**
- **Independent Safety Committee to review cohort data with preliminary results expected in near weeks**
- **Minimum Inhibitory Concentration (MIC) activity against bacteria already identified among existing clinical samples, a dose optimisation exercise for regulatory purposes**

Sydney Australia, 11 June 2024: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**), (the **Company**), the Company developing a New Class of Synthetic Anti-Infectives, is pleased to report it has successfully completed dosing of its latest cohort in its Phase I/II UTI/Urosepsis clinical trial, evaluating RECCE® 327 (R327) at fast infusion rates.

An Independent Safety Committee will review and evaluate the comprehensive data from the 6-subject cohort with preliminary results expected in near weeks.

Data from this trial is expected to pave the way for a Phase II UTI/Urosepsis efficacy trial, potentially establishing R327 as a frontline treatment. Administering antibiotics through rapid intravenous infusions has proven to be a safe, and effective method that significantly impacts patient treatment, reduces wait times, and alleviates nursing workloads worldwide¹.

Chief Executive Officer James Graham said "We have successfully reached a new milestone in this trial by administering a 4,000mg dose over a fast 20-minute infusion to all subjects, the highest dosage achieved so far in this clinical trial. This is a significant step forward in bringing us closer to establishing R327 as a leading treatment for those suffering from UTI/Urosepsis."

¹ [https://www.ijidonline.com/article/S1201-9712\(21\)00574-9/fulltext](https://www.ijidonline.com/article/S1201-9712(21)00574-9/fulltext)



The full efficacious potential of R327 via intravenous administration will be made available at the completion of this clinical trial in line with study protocol. More information on this trial can be found at the Australia New Zealand Clinical Trial Registry under the trial ID ACTRN12623000448640.

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

Media and Investor Relations

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 (R327) 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 (R435) as an orally administered therapy for bacterial infections; and RECCE® 529 (R529) for viral infections. Through their multi-layered mechanisms of action, Recce's anti-infectives have the potential to overcome the processes utilised by bacteria and viruses to overcome resistance – a current challenge facing existing antibiotics.

The World Health Organization (WHO) added R327, R435, and R529 to its list of antibacterial products in clinical development for priority pathogens, recognising Recce's efforts to combat antimicrobial resistance. The FDA granted R327 Qualified Infectious Disease Product designation under the Generating Antibiotic Initiatives Now (GAIN) Act, providing Fast Track Designation and 10 years of market exclusivity post approval. R327 is also included on The Pew Charitable Trusts' Global New Antibiotics in Development Pipeline as the sole synthetic polymer and sepsis drug candidate in development.

Recce wholly owns its automated manufacturing, supporting current clinical trials. Recce's anti-infective pipeline aims to address synergistic, unmet medical needs by leveraging its unique technologies.

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