

First Participants Dosed in Next Cohort Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial

Highlights:

- First participants (male/female) successfully dosed at 4,000mg (I.V.), over 20 minutes, 4,000mg highest dosage to date in this clinical trial
- RECCE® 327 (R327) tested at four fast I.V. infusion times (15-mins, 20-mins, 30-mins, 45-mins) over various dosage levels
- Minimum Inhibitory Concentration (MIC) activity against bacteria already identified among existing clinical samples, a dose optimisation exercise for regulatory purposes
- Remaining participants to be dosed over the coming days

Sydney Australia, 15 May 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 dosed first male and female participants in next cohort with RECCE® 327 (R327) at 4,000mg intravenously (I.V.) at a fast infusion rate of 20-minutes in its Phase I/II UTI/Urosepsis clinical trial.

The Company has explored multiple infusion times of R327 within this clinical trial; 15-mins, 20-mins, 30-mins and 45-mins. This is the highest dose (4,000mg) tested in participants in this trial with Minimum Inhibitory Concentration (MIC) activity against bacteria already identified among existing clinical samples with this increase in dose optimisation, an important exercise for regulatory purposes.

The full efficacious potential of R327 via I.V. 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.



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.