

Dosing Commenced in Next Cohort Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial

Highlights:

- Independent Safety Committee analysis complete; unanimously clears next clinical intravenous (I.V.) dosing go-ahead
- Next cohort of human participants will be dosed today at 3,000mg (I.V.), over 20 minutes
- RECCE® 327 (R327) (3,000mg) now tested at four infusion times (15-mins, 20-mins, 30-mins, 45-mins and 1-hour)
- Remaining participants to be dosed over the coming days
- R327 achieved multiple 'fast infusion' time stamps in line with intended future regulatory submissions

Sydney Australia, 12 March 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 the next cohort of human participants with RECCE® 327 (R327) at 3,000mg intravenously at a fast infusion rate of 20-minutes in its Phase I/II UTI/Urosepsis clinical trial.

The Company is exploring multiple infusion times; 15-mins, 20-mins, 30-mins, 45-mins, and 1-hour at 3,000mg, which is viewed as R327's optimal dosing therapeutic window.

The Company has established that the dose of 3,000mg, administered at varying infusion times between 15 mins – 60 mins, has been proven to be safe in participants.

In a parallel clinical program, R327 applied topically against Diabetic Foot Ulcer Infections recently demonstrated its efficacious potential against a broad range of antibiotic resistant infections. The efficacious potential of R327 via I.V. administration will only be made available at completion of this human clinical trial in line with study protocol.



Chief Executive Officer James Graham said "We're pleased to continue advancements within and surrounding our R327 clinical trials. The additional infusion time at 3,000mg over 20 minutes highlights a compelling safety profile with the potential to treat the millions of patients worldwide that suffer from UTI/Urosepsis each year."

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.

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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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