

ASX Announcement

First Subjects of Recruited Cohort Dosed Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial

Highlights:

- **First male and female subjects dosed; study is tracking to primary endpoints**
- **RECCE[®] 327 (3,000mg) over 15-minutes marking the fastest infusion rate of a high concentration, completed to date**
- **Cohort fully recruited with remaining subjects to be dosed over coming days**

SYDNEY Australia, 7 November 2023: Recce Pharmaceuticals Ltd (**ASX:RCE, FSE:R9Q**) (the **Company**), the Company developing a new class of Synthetic Anti-infectives, is pleased to report the first male and female subjects have completed dosing at the highest concentration of RECCE[®] 327 (R327) (3,000mg I.V.), within a fast infusion rate of 15-minutes in its Phase I/II UTI/Urosepsis clinical trial.

An independent safety committee, recently, unanimously concluded R327 is safe and well tolerated in male and female subjects at an infusion rate of 3000mg (I.V.), over 30 minutes. Since the previous cohort dosed, the Committee approved a faster infusion rate, double that of what was previously delivered over 30 minutes, now being delivered at 3,000mg over 15-minutes.

Chief Executive Officer James Graham said, “To be dosing at twice the speed of the last cohort to 3,000mg over 15-minutes via intravenous administration is a testament to the safety and tolerability profile of R327. Another important clinical milestone for the company, as we push towards achieving R327’s potential as a first-line treatment for the millions of patients suffering 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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