ASX Announcement



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

<u>Highlights:</u>

- Cohort dosing complete in male and female subjects; study is tracking to primary endpoints
- RECCE[®] 327 safe and well tolerated in male and female subjects at a faster infusion rate of 30 minutes of 3,000mg via intravenous administration
- Independent Safety Committee to review cohort data subject recruitment for next cohort underway

SYDNEY Australia, 22 September 2023: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing a new class of Synthetic Antiinfectives, is pleased to report Scientia Clinical Research has successfully completed cohort dosing of both male and female subjects in its Phase I/II UTI/Urosepsis clinical trial evaluating RECCE[®] 327 (R327) at faster infusion rates.

R327 was shown to be safe and well tolerated at a faster infusion rate of 30 minutes of 3,000mg, with an Independent Safety Committee reviewing complete cohort dosing data, expected to recommend go ahead, with recruitment well underway.

Chief Executive Officer James Graham said, "We are pleased to see R327 administered at a faster infusion rate of 3,000mg, reinforcing R327's safety profile among male and female subjects. These results further support R327's potential as a treatment option, positioning it as a therapy for patients suffering from UTI/Urosepsis, which is responsible for about 30% of all sepsis infections."

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 antiinfective pipeline seeks to exploit the unique capabilities of its technologies targeting synergistic, unmet medical needs.



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