ASX Announcement

Recce Pharmaceuticals
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ACN 124 849 065

Safety Committee Approves Next Dose of 3,000mg in Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial

Highlights:

- **Independent Safety Committee approves next Cohort dosing of RECCE® 327 (R327) at two faster infusion rates of 3,000mg via I.V. administration**
- **Independent Safety Committee unanimously agreed R327 is safe and well tolerated in male and female subjects at two faster infusion rates of 2,500mg via I.V. administration**
- **Next Cohort of subjects recruited – subject dosing to begin imminently**

SYDNEY Australia, 28 August 2023: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing a new class of Synthetic Anti-infectives, is pleased to report an Independent Safety Committee approved next cohort dosing at two faster infusion rates of 3,000mg. Furthermore, the committee unanimously agreed R327 at two faster infusion rates of 2,500mg is safe and well tolerated in male and female subjects. The next cohort of subjects have been recruited with dosing to begin imminently.

Chief Executive Officer of Recce Pharmaceuticals James Graham said "We are pleased to receive the go-ahead by the Independent Safety Committee to commence dosing of R327 at two faster infusion rates of 3,000mg. This reaffirms the committee's view that R327 is safe and well tolerated at two faster infusion rates of 2,500mg. Results from this trial will pave the way for R327 as a potential first-line treatment for patients suffering from UTI/Urosepsis."

UTI's are responsible for about 30% of all sepsis infections, defined as 'Urosepsis'[1]. R327's potential as a treatment option across the patient infectious disease journey (underlying infection>septic state) positions it for therapy in this area of unmet medical need. 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.

[1] https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-022-07538-5

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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