Recce Pharmaceuticals
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ACN 124 849 065

# Recce Pharmaceuticals Receives Ethics Approval to Start Phase I/II Clinical Trial of RECCE® 327

**Highlights:**

- **Phase I/II clinical trial of RECCE® 327 receives Human Research Ethics Committee approval for testing of faster infusion rates**
- **Study to be conducted at South Australia's CMAX clinical trial facility**
- **Site-initiation-visit to be conducted imminently with first patients to be dosed H1 2023**
- **Results received in this trial will pave the way for the Company's Phase II pre-sepsis UTI Efficacy Trial – as a potential 'first-line' treatment**

**SYDNEY Australia, 17 April 2023:** Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing a new class of Synthetic Anti-infectives, is pleased to announce it has received Human Research Ethics Committee (HREC) approval to start its Phase I/II intravenous (IV) clinical trial of its lead pipeline compound RECCE® 327 (R327) in healthy male and female subjects.

As announced 20 February 2023, the Phase I/II trial will look at assessing R327 as an intravenous dose at faster infusion rates (**15 minutes and 30 minutes**) across approximately 12 participants (**three cohorts**). During and following dosing, plasma and urine will be collected to evaluate R327's antibacterial and concentration effects.

First patient dosing is on track for H1 2023 at Adelaide's CMAX clinical trial facility with the trial expected to take approximately two months. The results of this Phase I/II trial will provide optimised dose levels and infusion rates for a Phase II pre-sepsis trial in patients with uncomplicated or recurrent Urinary Tract Infections (UTI). UTI's are responsible for approximately 30% of all sepsis infections, also known as Urosepsis.[1]

[1]Qiang XH, Yu TO, Li YN, Zhou LX. Prognosis Risk of Urosepsis in Critical Care Medicine: A Prospective Observational Study. Biomed Res Int. 2016;2016:9028924. doi: 10.1155/2016/9028924. Epub 2016 Feb 3. PMID: 26955639; PMCID: PMC4756185.

Administering the drug at faster rates, especially within a GP setting or an Acute patient setting, is important as antibiotics need to be administered faster to treat the infection. The 2021 Surviving Sepsis Campaign (SCC) guidelines strongly recommend that the administration of intravenous broad-spectrum antibiotics should be initiated as soon as possible, preferably within an hour of sepsis recognition.[2]

Recce Pharmaceuticals Non-Executive Director and Medical Monitor of the Clinical Trial Dr Alan Dunton said, "This is a very exciting time in the Company and a significant step in the right direction to provide a potential treatment for those suffering from uncomplicated and recurring UTIs, including those that progress to Urosepsis. This approval recognises the dedication and perseverance of all those involved, as we look to evaluate R327 as a broader anti-infective treatment."

Following HREC approval of this trial, the Company has now submitted registration to the Australia New Zealand Clinical Trials online registry.

This announcement has been approved for release by Recce Pharmaceuticals Board.

[2] https://pubmed.ncbi.nlm.nih.gov/34605781/



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Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

Media and Investor Relations

Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Jordyn Temperato
LifeSci Communications
jtemperato@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com

## 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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James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

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Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Jordyn Temperato
LifeSci Communications
jtemperato@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com