ASX Announcement

Recce Pharmaceuticals
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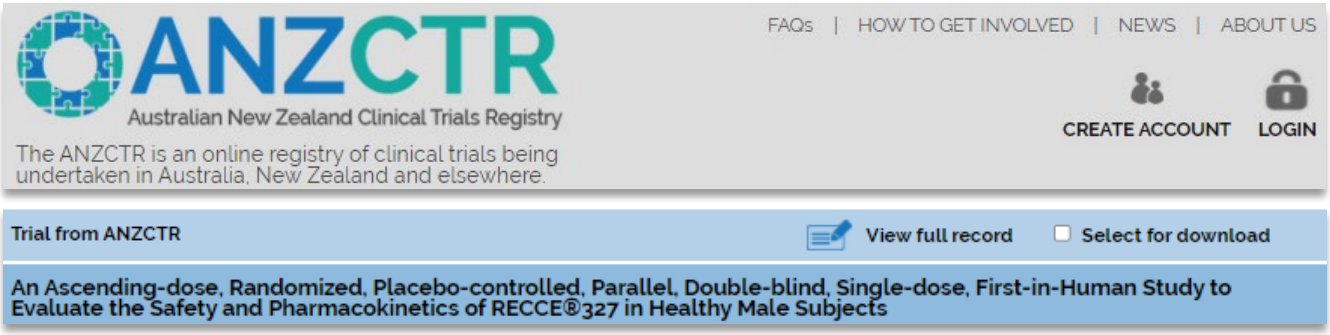
ACN 124 849 065

RECCE® 327 Trial Registered in the Australian New Zealand Clinical Trials Registry for Phase I Intravenous Study in Humans

Sydney Australia, 30 September 2021: Recce Pharmaceuticals Ltd (**ASX:RCE**) (**FSE:R9Q**), is pleased to announce trial registration for its lead compound RECCE® 327 (R327) in the Australian New Zealand Clinical Trial Registry (ANZCTR) for its Phase I Intravenous Study in Humans under the Trial ID ACTRN12621001313820p.



The ANZCTR is an online registry of clinical trials being undertaken in Australia, New Zealand and elsewhere. The ANZCTR includes trials from the full spectrum of therapeutic areas of pharmaceuticals. This registration represents one of the final administrative stages for the Phase I clinical trial of R327 to commence.

R327 represents a new class of broad-spectrum anti-infectives and was recently added to The Pew Charitable Trusts' list of *Non-traditional Products in Development to Combat Bacterial Infections*. Of the 36 candidates in clinical development, **R327 is the only synthetic polymer drug candidate and the only clinical stage antibiotic for the indication of sepsis – globally**[1].

The Company's clinical trial is registered under '*An Ascending-dose, Randomized, Placebo-controlled, Parallel, Double-blind, Single-dose, First-in-Human Study to Evaluate the Safety and Pharmacokinetics of RECCE® 327 in Healthy Male Subjects*'.

RECCE® 327 will be administered as a single dose via a 1-hour IV infusion across eight dose cohorts of 10 persons each, starting at 50 mg of R327 (8 subjects) or placebo (2 subjects). The trial will involve an in-patient Study Treatment Period (Day 1 and Day 2), and follow-up visit to the clinic at Day 7. Ethics Approval to start first patient dosing is in process and patient dosing anticipated for November at Adelaide's CMAX clinical trial facility. First cohort patient data remains on track to be available within the calendar year, with completion of the Phase I clinical trial expected to take approximately 12 months.

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

[1] https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2017/nontraditional-products-for-bacterial-infections-in-clinical-development

About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE, FSE: R9Q) is pioneering the development and commercialisation of New Classes 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 is unique and comprised of broad-spectrum synthetic polymer antibiotics RECCE® 327, RECCE® 435, and RECCE® 529 for viral infections with unique mechanisms of action against hyper-mutation on bacteria and viruses, respectively.

Patented lead candidate RECCE® 327 as an intravenous therapy, is being developed for treatment of serious and potentially life-threatening infections including sepsis due to Gram-positive and Gram-negative bacteria including their superbug forms. Recce's new antibiotic compound, RECCE® 435, has been formulated for oral use.

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 only synthetic polymer and sepsis drug candidate in development.

Recce wholly owns its automated manufacturing, ready to support first-in-human clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of RECCE® technologies targeting synergistic, unmet medical needs.

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