ASX Announcement

Recce Pharmaceuticals
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ACN 124 849 065

Recce Pharmaceuticals Receives Ethics Approval to Start Phase I Intravenous Clinical Trial of RECCE® 327

Highlights:

- **Phase I clinical trial of RECCE® 327 approved to start intravenous ascending-dose, randomized, placebo-controlled, parallel, double-blind, single-dose**
- **According to Pew Charitable Trusts, R327 is the only clinical stage antibiotic for the indication of sepsis - largest unmet medical need in human health**
- **First patient dosing December 2021 at Adelaide's CMAX clinical trial facility**

Sydney Australia, 25 October 2021: Recce Pharmaceuticals Ltd (ASX:RCE, FSE:R9Q), the Company developing New Classes of Synthetic Anti-infectives, today announced it has received Human Research Ethics Committee (HREC) approval to start its Phase I intravenous (IV) clinical trial evaluating the safety and pharmacokinetics of its lead compound, RECCE® 327 (R327).

The Phase I (IV) clinical trial is an ascending-dose, randomized, placebo-controlled, parallel, double-blind, single-dose study, evaluating the safety and pharmacokinetics of R327 in healthy male subjects. Approximately a total of 80 patients are to be enrolled. R327 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 treatment period (Day 1 and Day 2), and follow-up visit to the clinic at Day 7.

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]

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

First patient dosing is on track for December 2021 at Adelaide's CMAX clinical trial facility. The first cohort patient data remains on track to be available within the calendar year, with data readouts to be made available along the way and completion of the clinical trial expected to take approximately 12 months.

Ethics approval for this clinical trial is confirmation that Recce has completed the necessary pre-clinical safety and efficacy testing of R327 required to commence IV human clinical trials and runs in addition to a present Phase I/II Burns Wound Infection study (topical) at Fiona Stanley Hospital.

Recce Pharmaceuticals Chairman Dr. John Prendergast said, "Receiving human ethics approval is a momentous achievement for Recce and the clinicians seeking effective treatments to combat antibiotic-resistant bacteria. This milestone is a significant representation of the dedication and diligence our clinical and research team put into their day-to-day work as we continue to build on our clinical and commercial potential."

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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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