

ASX Announcement

Recce Pharmaceuticals Selects Australian-Based CMAX Clinical Trial Facility For Phase I Study of Synthetic Antibiotic RECCE® 327

Highlights:

- Phase I study to assess safety and tolerability of RECCE® 327 in healthy subjects as a single ascending dose
- Formal subject recruitment to open for enrolments shortly
- First subjects expected to be screened at the CMAX facility in Q4 2020

Sydney Australia, 10 September 2020: Recce Pharmaceuticals Ltd (**ASX: RCE**), the Company developing New Classes of Synthetic Anti-infectives, today announced it has selected South Australia's CMAX Clinical Research as the independent trial facility which will conduct a Phase I clinical study of its lead compound RECCE® 327.

The Phase I clinical trial is a randomised, double blind, placebo-controlled single-ascending dose study of 48 healthy adult subjects. The study seeks to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamic profile of RECCE® 327 following intravenous administration.

CMAX is one of Australia's largest, longest running and leading clinical trial facilities, located adjacent to The Royal Adelaide Hospital and centrally positioned in Adelaide. South Australia has one of the lowest rates of COVID-19 infection in the country, making it an attractive location for Recce's clinical studies. The clinical trial facility has consistently maintained world-class standards, and meets international regulatory authority data entry and quality requirements, including the European Medicines Agency and U.S Food and Drug Administration (FDA). CMAX has more than 30,000 registered patient volunteers on file.

CMAX CEO, Jane Kelly said, "The need for new classes of anti-infectives has never been greater. We are committed to supporting innovative medical research and look forward to assessing RECCE® 327's clinical utility in the infectious disease treatment landscape, through this Phase I human clinical study."



ASX: RCE

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CMAX Phase I Clinical Unit



CMAX Nursing Station for participant monitoring

Recce Pharmaceuticals Non-Executive Chairman, Dr. John Prendergast said, “CMAX has an impressive global regulatory history, database and diverse team of experts in clinical trials. As we prepare to enroll patients in our Phase I study, a critical milestone for Recce, we are confident in CMAX’s ability to leverage its established recruitment networks and deliver exceptional quality data.”

RECCE® 327 is a broad-spectrum synthetic antibiotic formulated using synthetic polymer technology to treat blood infections and sepsis derived from *Escherichia coli* and *Staphylococcus aureus* bacteria. It is the first new class of antibiotic in over three decades and is effective against both Gram-negative and Gram-positive bacteria, with a novel universal mechanism of action that maintains its antibacterial potency even with repeated use.

If you would like to volunteer for this clinical study please contact clinical@recce.com.au or visit <https://www.cmax.com.au>

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

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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE) 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 and 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 has been developed for the treatment of blood infections and sepsis derived from *E. coli* and *S. aureus* 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.

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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