Recce Pharmaceuticals
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**ASX Announcement**

# Recce Signs Phase I Human Clinical Trial Agreement of Synthetic Antibiotic RECCE® 327 in Healthy Human Subjects

## Highlights:

- **Phase I trial agreement with leading clinical research organization Parexel**
- **Human safety and tolerability study to assess intravenous infusion of RECCE® 327 in 40 healthy subjects as a single ascending dose**
- **Self-dosing by a respected NSW physician indicates encouraging safety profile**
- **Estimated clinical start-to-completion with data read-outs less than 12 months from now**
- **First patients expected to be dosed in second half of 2020**

**SYDNEY Australia, 8 April 2020:** Recce Pharmaceuticals Ltd (ASX: RCE), the company developing a new class of broad-spectrum synthetic antibiotics, today announced it has formalised a Phase I clinical trial agreement to conduct a first-in-human study of its lead compound RECCE® 327 in 40 healthy subjects.

The Phase I clinical study of RECCE® 327 will be conducted at a specialised clinical trial facility in Australia, independent of the hospital system. This initiative seeks to ensure continuity of the independent study and not add to infectious disease pressures for beds around the country. The first patients in this study are expected to be dosed in the second half of 2020.

The randomized, double blind, placebo-controlled single-ascending dose study will involve up to 40 healthy subjects to evaluate safety, tolerability, pharmacokinetic and pharmacodynamic properties of RECCE® 327; clinical start-to-completion expected within 12 months from now, with regular interim data updates.

Recce Chairman Dr. John Prendergast said, “The formalisation of the clinical trial agreement is a major milestone towards advancing RECCE® 327 through the clinic. It brings us a step closer to addressing the rising rates of antibiotic resistance, with a synthetic antibiotic that has shown extraordinary preclinical potential to fight off a broad range of bacterial infections, including superbug forms, even with repeated use.”

In anticipation, a respected physician at a leading teaching Australian hospital performed a self-dosing treatment that showed No Observed Adverse Effect Levels. The protocol followed saw an

escalation of 1ml undiluted (neat) RECCE® 327 via buccal administration. Blood samples were taken, analysed for haematology and clinical biochemistry parameters by a third-party, and results were found to be normal. Further analysis is expected to be taken on the samples to determine concentration levels of RECCE® 327 in the blood.

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 sees its antibacterial potency continue even with repeated use.

Sepsis is a potentially life-threatening condition mostly caused by bacterial infection in the blood and results in the immune system mounting a hyperactive inflammatory response to the bacteria/toxins, which can quickly lead to tissue and organ injury, and ultimately death. There are currently no drug therapies available specifically targeted for the treatment of sepsis, and therefore there is a desperate and unmet medical need for new, safe and efficacious treatments. According to the World Health Organization, sepsis is estimated to affect more than 30 million people worldwide every year, potentially leading to six million deaths.

This announcement has been approved for release by Recce Pharmaceutical's Chairman


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**About Recce Pharmaceuticals Ltd**

Recce Pharmaceuticals Ltd (ASX: RCE) is pioneering the development and commercialisation of a New Class of Synthetic Antibiotics with Broad Spectrum activity designed to address the urgent global health problem of antibiotic resistant superbugs.

Recce antibiotics are unique – their potency does not diminish even with repeated use, which is a common failure associated with existing antibiotic use and the resulting emergence of resistant superbugs.

Patented lead candidate RECCE® 327, wholly owned and manufactured in Australia, has been developed for the treatment of blood infections and sepsis derived from *E. coli* and *S. aureus* bacteria – including their superbug forms.

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.


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