

## ASX Announcement

# Fiona Stanley Hospital Phase I/II Clinical Trial Evaluating Topical Spray-On Antibiotic RECCE® 327 on Chronic Burn Wounds

### Highlights:

- **Phase I/II trial agreement with Fiona Stanley Hospital (Burns Unit) in Perth Western Australia**
- **Study led by world leading burn treatment specialists**
- **Study will assess safety and efficacy of RECCE® 327 against a broad range of infectious disease on chronic burn wounds in up to 30 patients**
- **RECCE® 327 formulated as new spray-on antibiotic for chronic burn wounds**
- **First patients to be dosed in present quarter**

**Sydney Australia, 16 February 2021:** Recce Pharmaceuticals Ltd (ASX:RCE), the Company developing New Classes of Synthetic Anti-Infectives, today announced it has formalised an agreement with Fiona Stanley Hospital for a Phase I/II clinical trial to assess the potential of RECCE® 327's new spray-on, broad-spectrum antibiotic for the treatment of topical burn wound infections.

The trial investigators are Dr Edward Raby (Clinical Microbiologist and Infectious Diseases expert at Royal Perth and Fiona Stanley Hospitals); Dr Chris Heath (Head of Infectious Diseases at Fiona Stanley Hospital); and Professor Fiona Wood (Director of State Adult Burns Unit at Fiona Stanley Hospital), internationally renowned burns surgeon, known for pioneering the development of 'spray-on skin'.

*Dr Edward Raby said, "Antibiotic resistant infection is a major issue after burns injury. Our team is keen to identify and add new treatments with the potential to overcome antibiotic resistance and improve patient's lives. We look forward to evaluating this new spray-on antibiotic."*

The Phase I/II topical study will enrol up to 30 patients and be conducted at Fiona Stanley Hospital Burns Unit in Perth Western Australia. The study will assess the safety and efficacy of RECCE® 327 as a broad spectrum spray-on antibiotic for patients with Gram-positive and Gram-negative



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bacterial burn wound infections; expanding to a comparative effectiveness study based on the data. Over 14 days, 10 patients will receive RECCE® 327 daily, while 20 patients will receive treatment three times per week. The first patients to be dosed in the present quarter.

Burn wound specialists will oversee delivery of RECCE® 327 in a spray-on formulation, specifically developed for the study. The product has been produced at the Company's manufacturing facility to the same human clinical study standards as the previously announced Phase I intravenous clinical trial. It is anticipated the two studies will run in parallel, demonstrating the broad administration capabilities of RECCE® 327.

Recce Pharmaceuticals Chairman Dr. John Prendergast said, "We look forward to working with the world-leading team at Fiona Stanley Hospital in advancing new treatment options for burns victims at increased risk of infection from multidrug resistant organisms. Based on promising results from preclinical studies, we believe RECCE® 327 has potential to make a significant impact in treating infections, which continue to pose a challenge to the long-term survival of patients in burns units."

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

#### Chief Executive Officer

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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<sup>®</sup> 327, RECCE<sup>®</sup> 435, and RECCE<sup>®</sup> 529 for viral infections with unique mechanisms of action against hyper-mutation on bacteria and viruses, respectively.

Patented lead candidate RECCE<sup>®</sup> 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<sup>®</sup> 435, has been formulated for oral use.

The FDA has awarded RECCE<sup>®</sup> 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<sup>®</sup> technologies targeting synergistic, unmet medical needs.

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