ASX Announcement

Recce Pharmaceuticals
recce.com.au
ACN 124 849 065

Recce Pharmaceuticals Receives Ethics Approval to Start Phase I/II Burns Wound Study in Perth Western Australia

Highlights:

- **Study will assess safety and efficacy of RECCE® 327 against a broad range of infectious bacteria on chronic burn wounds in up to 30 patients over two week period**
- **Study anticipated to be sponsored by South Metropolitan Health Service, Department of Health, Government of Western Australia (WA)**
- **Fiona Stanley Hospital (Burns Unit) in Perth Western Australia identified as study site**

Sydney Australia, 16 October 2020: Recce Pharmaceuticals Ltd (**ASX: RCE**), the Company developing New Classes of Synthetic Anti-infectives, today announced it has received Human Research Ethics Committee (HREC) approval to start a Phase I/II clinical trial of its broad-spectrum antibiotic RECCE® 327 on patients with infected burn wounds.

The clinical study is anticipated to be sponsored by the South Metropolitan Health Service, Department of Health, Government of Western Australia. The Fiona Stanley Hospital has been nominated as the study site and a separate trial agreement will be finalised in due course.

The Phase I/II topical study will assess RECCE® 327 as a broad-spectrum antibiotic for patients with Gram-positive and Gram-negative bacterial burn wound infections.

The trial will involve up to 30 patients to assess safety and efficacy of RECCE® 327 before expanding to a comparative effectiveness study based on the data. Over 14 days, 10 patients will receive RECCE® 327 daily while a further 20 receive treatment three times per week.

Investigators will review the study data for clinical efficacy and toxicity before deciding to expand the trial to assess the compound's efficacy against the current best standards of care.

Burn wounds specialists will oversee delivery of RECCE® 327 via a spray-on formulation, specially developed for the study. The product has been produced at the Company's manufacturing facilty 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 broad administration capabilities of RECCE® 327.

Ethics approval is confirmation Recce has completed the necessary pre-clinical safety and efficacy testing of RECCE® 327 required to commence human clinical trials.

Recce Pharmaceuticals Chairman Dr John Prendergast said, "Human ethics approval is another milestone for Recce and the clinicians seeking effective treatments to combat the scourge of antibiotic resistant bacteria. Achieving this goal speaks to the dedication of our clinical and research team as we continue to build on our clinical and commercial potential."

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

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
+61 (02) 8075 4585
james.graham@recce.com.au

Media and Investor Relations (AU)
Andrew Geddes
CityPR
+61 (02) 9267 4511
ageddes@citypublicrelations.com.au

Media and Investor Relations (USA)
Meredith Sosulski, PhD
LifeSci Communications
+1 929 469 3851
msosulski@lifescicomms.com

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.

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
+61 (02) 8075 4585
james.graham@recce.com.au

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Andrew Geddes
CityPR
+61 (02) 9267 4511
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Media and Investor Relations (USA)
Meredith Sosulski, PhD
LifeSci Communications
+1 929 469 3851
msosulski@lifescicomms.com