ASX Announcement

Recce Pharmaceuticals
recce.com.au
ACN 124 849 065

Recce Pharmaceuticals Receives Ethics Approval to Start Phase I/II Diabetic Foot Ulcer Study

Highlights:

- **Phase I/II clinical trial of RECCE® 327 (R327) approved to start at South West Sydney Limb Preservation and Wound Research Unit, located at the Ingham Institute of Medical Research**
- **Study will assess safety and efficacy of R327 on mild skin and soft tissue diabetic foot infections in up to 32 patients**
- **Patient population readily available; first patients to be dosed Q1 2023**

SYDNEY Australia, 9 December 2022: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing a New Class of Synthetic Anti-infectives, today announced it has received Human Research Ethics Committee (HREC) approval to start its Phase I/II clinical trial assessing R327 as a spray-on, broad-spectrum antibiotic therapy for mild skin and soft tissue diabetic foot infections (DFI).

The Clinical Investigation Team comprises Professor Hugh Dickson OAM as Principal Investigator (Consultant Physician in Ambulatory Care), Associate Professor Slade Jensen (Chair of Infectious Diseases and Microbiology and Western Sydney University, School of Medicine), a team of specialist Associate Investigators and the Ingham Institute of Applied Medical Research.

Principal Investigator, Professor Dickson said “The research indicates that RECCE® 327 may be effective in treating patients with diabetic foot infections. The team hopes that its early promise is fulfilled in this study in our patients.”

The Phase I/II clinical trial is a single-centre, prospective, interventional study assessing the safety and efficacy of R327 as a broad-spectrum, topical anti-infective treatment for patients with mild skin and soft tissue DFI.

The trial will enrol up to 32 patients and be conducted at Sydney South West's Limb Preservation and Wound Research Unit. This unit was chosen for its innovative and ground-breaking focus on wounds of the limbs and limb loss, an under-researched area in Australian healthcare. Sydney's South West also has one of the highest prevalence rates of diabetes in NSW and complications from this disease can significantly impact people's quality of life. The Company expects first patients will be dosed Q1 2023.

The Company is exploring R327 as a preventative treatment for DFI, as studies in the United States have shown between 14-24% percent of patients with diabetes who develop a foot ulcer will require an amputation, and foot ulceration precedes 85% of diabetes-related amputations[1]. Moreover, the total medical costs for treating diabetic foot diseases in the United States is US $9-13 billion every year[2].

Ethics approval for this clinical trial is confirmation that the Company has completed the necessary pre-clinical safety and efficacy testing of R327 required to commence human clinical trials and runs in addition to its other ongoing clinical trials. 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.

The study is made possible thanks to the NSW Government Department of Health, at a cost of AUD <$500,000.

Recce Pharmaceuticals Chief Executive Officer James Graham said, "Receiving HREC approval is yet another milestone for Recce and the clinicians seeking to find an effective therapeutic treatment against DFI. This achievement speaks to Recce's track record of HREC approvals already received and the dedication of our clinical and research team, as we look forward to building out our topical programs."

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

[1] *https://surgery.ucsf.edu/conditions--procedures/diabetic-foot-ulcers.aspx*

[2] *Zhang P. et al. – "Global epidemiology of diabetic foot ulceration: A systematic review and meta-analysis" (dagger) - Ann. Med. 2017;49:106–116.*

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
+61 (02) 9256 2571
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)
Jordyn Temperato
LifeSci Communications
jtemperato@lifescicomms.com

Chief Executive Officer

James Graham
Recce Pharmaceuticals Ltd
+61 (02) 9256 2571
james.graham@recce.com.au

Media and Investor Relations (AU)

Andrew Geddes
CityPR
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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: **RCE**, FSE: **R9Q**) is developing 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 includes three patented, broad-spectrum, synthetic polymer anti-infectives: RECCE® 327 as an intravenous and topical therapy that is being developed for the treatment of serious and potentially life-threatening infections due to Gram-positive and Gram-negative bacteria including their superbug forms; RECCE® 435 as an orally administered therapy for bacterial infections; and RECCE® 529 for viral infections. Through their multi-layered mechanisms of action, Recce's anti-infectives have the potential to overcome the hypercellular mutation of bacteria and viruses – the challenge of all existing antibiotics to date.

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 world's only synthetic polymer and sepsis drug candidate in development. RECCE® 327 is not yet market approved for use in humans with further clinical testing required to fully evaluate safety and efficacy.

Recce wholly owns its automated manufacturing, which is supporting present clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of its technologies targeting synergistic, unmet medical needs.

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James Graham
Recce Pharmaceuticals Ltd
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