For personal use only

ASX Announcement

Phase I/II Clinical Trial Results for Diabetic Foot Infection Treatment - Positive Human Efficacy Data to Support Site Expansion

Highlights:

- **Phase I/II clinical trial assessing the safety and efficacy of RECCE® 327 (R327), a broad-spectrum anti-infective, given as a topical treatment – study met all primary endpoints**
- **R327 well-tolerated in all patients; diabetic foot infections (DFI) resolved/cured**
- **Patients with mild skin and soft tissue DFI including multidrug-resistant Gram-positive and Gram-negative pathogens**
- **Human efficacy data to support imminent domestic and international site expansion**

Sydney Australia, 18 January 2024: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**), (the **Company**), the Company developing a New Class of Synthetic Anti-Infectives, is pleased to report an update on its Phase I/II diabetic foot infection clinical trial.

This Phase I/II clinical trial is an interventional study assessing the safety and efficacy of RECCE® 327 (R327) as a topical broad-spectrum anti-infective treatment for patients with mild skin and soft tissue diabetic foot infections (DFI). Patients were treated either daily or every second day, for 14 days.

The study achieved its primary endpoints of resolving/curing bacterial infections in DFI. Following this success, Recce will look to expand clinical sites domestically and internationally, in the interest of accessing a greater patient population.

Summary of Treated Patients

	Application Frequency	Age (yrs)/ Sex	Wound Location	Clinical Response
Patient 1	**Daily**	32 / M	Left forefoot lateral aspect	Escalated therapy*
Patient 2	**Second Daily**	55 / M	Right hallux plantar aspect	**Infection resolved/cured**
Patient 3	**Second Daily**	51 / M	Left forefoot plantar aspect	**Infection resolved/cured**
Patient 4	**Daily**	70 / M	Left forefoot plantar aspect	**Infection resolved/cured**
Patient 5	**Daily**	64 / M	Right hallux dorsal aspect	**Infection resolved/cured**

*Patient was on systemic therapy prior to commencing R327 treatment. Patient suffered from several comorbidities and escalated to systemic therapy.

Patient 1 (Daily) – (Methicillin-Resistant *Staphylococcus aureus* infection)*

32-year-old male with a four-year history of Type 2 Diabetes Mellitus, coupled with various cardiovascular risk factors such as Hypertension, Obesity and Dyslipidaemia (abnormally elevated cholesterol in the blood).

The 235kg patient was recruited with a significant neuropathic (infection that damages/diseases one or more nerves) wound on the left side of his left foot. The patient was on systemic therapy and was required to stop his treatment to meet clinical trial protocol (R327 topically applied only). Day 15 (midpoint) post R327 treatment, the initial redness of the wound and swelling of the foot had minimised and reduced in size. Due to patient comorbidities and complexity of the significant wound, the patient was returned to addition of systemic therapy, which disqualified the patient from clinical trial from there. Day 28-day follow-up showed the infection was however resolved, and all therapy ceased.

Patient 2 (Second Daily) – Infection Resolved/Cured (*Staphylococcus aureus*, mixed skin flora and Coliforms)

55-year-old male with a 23-year history of Type 2 Diabetes Mellitus who was suffering from an active neuropathic DFI wound on his right big toe and has had recurrent infections unresponsive to several antibiotics.

After three doses of R327 treatment (midpoint – day 7), a significant reduction of the infection was observed, with the wound drying and rapidly improving. By the endpoint (day 14) of the patient's treatment, the infection was resolved/cured; no recurrence of infection was identified. R327 was well-tolerated and effective throughout the patient's treatment therapy.

Patient 3 (Second Daily) – Infection Resolved/Cured (*Staphylococcus aureus*, mixed skin flora and mixed coliforms)

52-year-old male, with a 16-year history of Type 2 Diabetes Mellitus with a DFI wound on the left side of his left foot.

After three doses of R327 treatment (midpoint – day 7), a significant reduction of the infection was observed with infection rapidly clearing. At the endpoint (day 14) of the R327 treatment, the infection had been resolved/cured. No follow-ups were required, as R327 was well-tolerated and effective throughout the patient's treatment therapy.

For personal use only

recce.com.au
ACN 124 849 065

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

Media and Investor Relations

Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Jordyn Temperato
LifeSci Communications
jtemperato@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com

For personal use only

Patient 4 (Daily) – Infection Resolved/Cured in half the treatment time (Mixed skin flora)

70-year-old male, with Type 2 Diabetes Mellitus and a DFI wound on the left side of his left foot.

The patient was observed at the midpoint (day 7) of the R327 treatment with the infection resolved/cured in half the time. No follow-ups were required, as R327 was well-tolerated and effective throughout the patient's treatment therapy.

Patient 5 (Daily) – Infection Resolved/Cured (Mixed skin flora and Coliforms)

64-year-old male, with Type 2 Diabetes Mellitus and a DFI wound on his right foot.

At the midpoint (day 7) of R327 treatment, a significant reduction of the infection was observed with the infection improving. At the endpoint (day 14) of the R327 treatment, the infection had been resolved/cured. R327 was well-tolerated and effective throughout the patient's treatment therapy.

Diabetes is the leading cause of non-traumatic lower extremity amputations in the United States (U.S.) with 14-24% of patients with diabetes (who develop a foot ulcer) requiring amputation. Furthermore, foot ulceration leads to 85% of diabetes-related amputations. Treating diabetic foot diseases in the U.S. costs USD $9-13 billion every year[1]. A worldwide meta-analysis reported diverse bacteria from DFI, and the organism most commonly identified was *Staphylococcus aureus* with a pooled prevalence estimate of 18.0%[2].

Chief Executive Officer of Recce Pharmaceuticals James Graham said, "We are pleased that the Phase I/II clinical trial has met all primary endpoints, and produced efficacy data to support R327 to be used as topical agent. We look forward to expanding the study by accessing a global patient population and further enhancing our portfolio of human efficacy data."

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

[1] Zhang P. et al. – "Global epidemiology of diabetic foot ulceration: A systematic review and meta-analysis" (dagger) - Ann. Med. 2017;49:106–116.
[2] https://www.nature.com/articles/s41598-023-41882-z

recce.com.au
ACN 124 849 065

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

Media and Investor Relations

Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Jordyn Temperato
LifeSci Communications
jtemperato@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com

About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: **RCE**, FSE: **R9Q**) is developing a New Class 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.

For personal use only

recce.com.au
ACN 124 849 065

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

Media and Investor Relations

Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Jordyn Temperato
LifeSci Communications
jtemperato@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com