ASX Announcement

Patients Dosed in RECCE® 327 Phase I/II Diabetic Foot Infection Clinical Trial

Highlights:

- **Patients dosed in 14-day RECCE® 327 (R327) topical Phase I/II Diabetic Foot Infection (DFI) clinical trial**
- **Clinical trial underway at South West Sydney Limb Preservation and Wound Research Unit located at Liverpool Hospital NSW; daily dose visitation of out-patient nurses**
- **Interim data readouts expected later this quarter (Q3 CY23) of patients dosed with R327 as a topical administration**
- **Largest DFI Study underway in Australia at this time[1]**

SYDNEY Australia, 22 August 2023: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing a new class of Synthetic Anti-infectives, is pleased to announce its Phase I/II Diabetic Foot Infections (DFI) clinical trial has commenced dosing of patients at Liverpool Hospitals South West's Sydney Limb Preservation and Wound Research Unit.

The Phase I/II clinical trial is a prospective, interventional study assessing the safety and efficacy of RECCE® 327 (R327) as a topical broad-spectrum, dosed daily over 14 days as a potential topical anti-infective treatment for patients with mild skin and soft tissue diabetic foot infections (DFI).

Each year the High-Risk Foot Service (HRFS) at Liverpool Hospital manages approximately 800 patients presenting with complex foot disease, with over 80% occurring in people with diabetes. The study is supported by out-patient (at home) nurses trained in R327 Diabetic Foot Infection (DFI) treatment protocols, ensuring daily dosing, wound health, while capturing a broadened patient population.

[1] https://www.anzctr.org.au – DFI Clinical Trials

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.[2] Treating diabetic foot diseases in the U.S. costs USD $9-13 billion every year.[3]

Chief Executive Officer of Recce Pharmaceuticals James Graham said "R327 topical dosing of multiple patients in Australia's largest DFI study is another welcomed advance to the Company's infectious disease portfolio of clinical programs."

More information on this trial can be found at the Australia New Zealand Clinical Trial Registry under the trial ID ACTRN12623000056695 – Proof of concept study of RECCE® 327 topical anti-infective therapy for mild skin and soft tissue diabetes foot infections (DFIs).

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

[2] https://surgery.ucsf.edu/conditions--procedures/diabetic-foot-ulcers.aspx
[3] Zhang P. et al. – "Global epidemiology of diabetic foot ulceration: A systematic review and meta-analysis" (dagger) - Ann. Med. 2017;49:106–116.

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.

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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