ASX Announcement

Recce Pharmaceuticals
recce.com.au
ACN 124 849 065

Diabetic Foot Infections Clinical Trial Update
Outpatient Nurses Appointed

Highlights:

- **Patients in Phase I/II clinical trial of RECCE® 327 (R327) now supported by in-home (out-patient) nurses trained in R327 diabetic foot infection (DFI) treatment protocols, per Australian Clinical Trial Guidelines**
- **Appointment of leading healthcare provider Ascott – broadening treatable DFI trial patient population – increased probability of protocol adherence and dosing completion through out-patient nursing**
- **Largest DFI study underway in Australia at this time[1]**

SYDNEY Australia, 29 May 2023: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing a new class of Synthetic Anti-infectives, is pleased to announce it has awarded and on-boarded outpatient nurses from leading healthcare provider Ascott (an IQVIA Company) broadening the Company's Diabetic Foot Infection (DFI) trial patient population.

The Phase I/II clinical trial is a 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 diabetic foot infections.

The Company is exploring R327 as a treatment for DFI. In the United States, 14-24% of patients with diabetes who develop a foot ulcer will require an amputation, and foot ulceration precedes 85% of diabetes-related amputations.[2] Treating diabetic foot diseases in the United States costs US$9-13 billion every year. [3]

Under R327 dosing protocols, Ascott nurses will provide and replicate the high level of care patients would receive if attending on-site clinical trial visits, increasing the probability of protocol adherence and dosing completion. The in-home nurses will be adhering to national

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

and international clinical trial regulatory requirements and perform services including (but not limited to) collecting vital signs, conducting basic wound assessment and cleaning, administering R327 as a topical agent, and performing concomitant medication and adverse event monitoring and recording.

Ascott has serviced over 22 years of clinical experience and expertise across the pharmaceutical and health care industry, which includes medical devices, clinic support, nurse support, patient engagement programs and 12 years' clinical experience supporting in-home clinical trials.

Currently supporting 29 active clinical trials across Australia and New Zealand in the home, Ascott's dedicated nurses (approximately 300) interact with more than 25,000 patients per year, with the ability to implement scalable solutions to quickly meet demand.

Recce Pharmaceuticals Chief Executive Officer James Graham said, "We are thrilled to further strengthen our Phase I/II clinical trial with the support of Ascott. As the global search for an effective treatment for Diabetic Foot Infections continues, Recce is leading the way by conducting Australia's largest DFI study. The Company continues to address unmet medical needs through our portfolio of clinical programs."

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

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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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