ASX Announcement

Australian HREC Approves Active-Controlled Comparator Study Design for Pivotal Phase 3 DFI Trial

Highlights:

- **HREC approval received for a further protocol amendment to the Company's pivotal Phase 3 clinical trial of RECCE® 327 Topical Gel (R327G) in Diabetic Foot Infections (DFI) in Australia, adding a new randomised, active-controlled, non-inferiority study arm**
- **Expansion builds on existing pivotal Phase 3 program overseas, reinforcing Recce's global regulatory strategy targeting approvals across Australia, the United States, MENA and ASEAN regions**
- **DFI study arm randomises 208 patients between R327G and one of four physician-selected comparator antibiotics**
- **Head-to-head comparison against existing antibiotics used for treating DFIs – there is no specific existing standard of care**
- **If successful, R327G positioned as the first standard of care treatment for DFIs**
- **Patient dosing continues under the existing trial protocol, with recruitment and treatment ongoing ahead of implementation of this newly approved amendment**

Sydney Australia, 19 August 2026: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**), (**Recce** or **the Company**), a leading developer of synthetic anti-infectives, is pleased to announce that the Human Research Ethics Committee (HREC) has approved an amendment to the protocol for the Company's pivotal Phase 3 clinical trial of RECCE® 327 Topical Gel (R327G) for the treatment of Diabetic Foot Infections (DFI) in Australia.

Patient dosing in the Phase 3 trial is well underway, with active recruitment and treatment including mild to moderate DFI patients continuing to progress. The newly approved amendment adds a randomised, active-controlled, non-inferiority study in DFI, enrolling a total of 208 participants randomised between R327G and a physician-selected antibiotic — enabling the Company to generate comparative clinical data for R327G against established antibiotic treatment options used in the management of DFI.

The amended inclusion criteria also allow participants randomised to R327G to receive treatment for each qualifying DFI they experience during the study, enabling multiple efficacy assessments to be captured per participant where applicable. This is intended to increase the volume and depth of efficacy data generated within the study.

The Phase 3 trial amendment positions R327G to go head-to-head against multiple existing antibiotics, generating comparative data relevant to its potential as a treatment for DFIs. A planned interim analysis will be conducted by the Independent Data Monitoring Committee after 104 total participants have been enrolled, randomised, treated, and followed to the end of treatment or withdrawn prematurely.

Treatment selection for DFI is guided by factors including the suspected or known causative pathogen(s) and their antibiotic susceptibility, infection severity, and patient-specific factors such as prior antibiotic exposure, allergy history, and risk of methicillin-resistant *Staphylococcus aureus* (MRSA) — with therapy refined where appropriate according to culture and sensitivity results. [1]

The updated protocol also introduces wound imaging, which uses calibrated digital photography to capture standardised, objective wound measurements. Images add a further layer of objective assessment of the infection alongside investigator evaluation and strengthen the data package supporting global regulatory submissions.

This Australian Phase 3 program reinforces the Company's ongoing pivotal Phase 3 DFI program in Indonesia and stands as a core pillar of Recce's global development and regulatory strategy, spanning Australia, the United States, MENA, and ASEAN markets.

Recce Pharmaceuticals Chief Executive Officer, James Graham, said: “This protocol amendment reflects the significant advancements being made in our Phase 3 Clinical Programs, with continued engagement from trial sites and clinicians. We look forward to patient dosing continuing and generating data for R327G against standard of care antibiotics. R327G has the potential to become the first standard of care used by physicians for the treatment of DFIs.”

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

[1] South Australia Health. Diabetic Foot Infections: Antibiotic Management Clinical Guideline. Version 1.0. 2019. Available at: sahealth.sa.gov.au

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.

Recce's anti-infective pipeline includes three patented, broad-spectrum, synthetic polymer anti-infectives: RECCE® 327 (R327) 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 (R435) as an orally administered therapy for bacterial infections; and RECCE® 529 (R529) for viral infections. Through their multi-layered mechanisms of action, Recce's anti-infectives have the potential to overcome the processes utilised by bacteria and viruses to overcome resistance – a current challenge facing existing antibiotics.

The World Health Organization (WHO) added R327, R435, and R529 to its list of antibacterial products in clinical development for priority pathogens, recognising Recce's efforts to combat antimicrobial resistance. The FDA granted R327 Qualified Infectious Disease Product designation under the Generating Antibiotic Incentives Now (GAIN) Act, providing Fast Track Designation and 10 years of market exclusivity post approval. R327 is also included on The Pew Charitable Trusts' Global New Antibiotics in Development Pipeline as the sole synthetic polymer and sepsis drug candidate in development.

Recce wholly owns its automated manufacturing, supporting current clinical trials. Recce's anti-infective pipeline aims to address synergistic, unmet medical needs by leveraging its unique technologies.

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