ASX Announcement

Recce Pharmaceuticals
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HREC Approval Accelerates and Expands Recce Pharmaceuticals Global Regulatory Strategy for Diabetic Foot Ulcer Infections

Highlights:

- **HREC approval received to advance the Company's clinical trial of RECCE® 327 Topical Gel (R327G) in Australia to a pivotal Phase 3 trial for Diabetic Foot Ulcer Infections (DFI)**
- **Protocol amendment expands patient eligibility to include Moderate DFI, significantly broadening recruitment; Mild and Moderate DFI collectively account for approximately 80% of DFI presentations**
- **Given R327G's excellent safety profile, the study has also been approved to include infected ulcers below the knee in addition to infected foot ulcers. This will enable an additional primary endpoint analysis based on individual ulcers, increasing study power and enhancing the probability of success**
- **With the ability to enrol moderate patients, Recce has advanced its global regulatory strategy having two registrational/pivotal Phase 3 trials operating in Indonesia and Australia (conducted to US FDA regulatory standards), forming the cornerstone of its global DFI registration strategy targeting approvals across Australia, the United States, MENA and ASEAN markets**
- **These expanded study parameters accelerate patient recruitment, with expected full enrolment by the end of 2027**
- **Currently, the Australian pivotal Phase 3 trial has 18 patients completed of an anticipated 200-patient study. An interim analysis will be performed when 50% of patients have completed treatment**
- **Previously completed Phase II clinical data demonstrated strong efficacy, achieving a 93% primary efficacy endpoint at Day 14 and 86% clinical response by Day 7 in ABSSSI/DFI patients**
- **Advancement of the DFI clinical program further supports the Company's recently signed non-binding term sheet with a leading Middle Eastern pharmaceutical company for exclusive licensing across MENA countries**

Sydney Australia, 22 June 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 a protocol amendment to the Company's Phase II clinical trial of RECCE® 327 Topical Gel (R327G) for the treatment of Diabetic Foot Infections (DFI), advancing the study to a Pivotal Phase 3 clinical trial.

This approval builds upon the previously completed Phase II ABSSSI/DFI clinical trial that successfully achieved a 93% primary efficacy endpoint at Day 14 and 86% clinical response by Day 7, with no serious adverse events reported.

The study has now been elevated to Phase 3 status, with all newly enrolled patients entering under a revised pivotal Phase 3 protocol. A pivotal Phase 3 trial is considered a registrational study designed to generate the safety and efficacy data required to support regulatory approval applications. The trial has treated 18 of a possible 200 total patients, with an interim data analysis performed when 50% of patients have completed treatment. The trial is being conducted to TGA and US FDA regulatory standards, with expected full enrolment by the end of 2027.

The HREC-approved protocol amendment expands eligibility to include Moderate DFI patients in addition to Mild DFI patients which represent approximately 80% of diabetic foot infection presentations[1], significantly broadening the recruitment patient population for R327G.

Given R327G's favourable safety profile, the study has also been expanded to include infected ulcers below the knee, enabling an additional primary endpoint analysis at the individual ulcer level, increasing study power and enhancing the probability of success. The primary endpoint assesses clinical response according to the Lipsky Scale, with secondary endpoints evaluating total wound score and the safety profile of R327G.

The Company now has two parallel Phase 3 programs in Australia and Indonesia, together forming the cornerstone of Recce's global DFI registration strategy targeting approvals for R327G in Australia, US, MENA and ASEAN, and further supports the Company's recently executed non-binding licensing term sheet for exclusive commercialisation of R327G across 12 MENA countries.

DFI is a leading cause of hospitalisation and lower extremity amputation in people living with diabetes, carrying significant morbidity and reduced life expectancy. In Australia and the United States, diabetes-related foot infections contribute to more than 4,400 and 130,000 lower extremity amputations respectively, with five-year post-amputation mortality of approximately 50%[2],

1 Lavery LA, Armstrong DG, Murdoch DP, Peters EJG, Lipsky BA. Validation of the Infectious Diseases Society of America's diabetic foot infection classification system. Clinical Infectious Diseases. 2007;44(4):562–565.
2 Matheson EM, Bragg SW, Blackwelder RS. Diabetes-related foot infections: diagnosis and treatment. American Family Physician. 2021;104(4):386–394.

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exceeding the mortality rate of many cancers. Australia has the second highest amputation rate in the developed world, at a cost of approximately $875 million annually to the health system.[3] [4] With antimicrobial resistance driving treatment failure in DFI, the need for novel topical anti-infective therapies is acute and growing.

Recce Pharmaceuticals Chief Executive Officer, James Graham, said: “Receiving HREC approval to expand and accelerate our Australian Phase 3 program is a significant milestone for Recce and for patients with diabetic foot infections. With two concurrent Phase 3 programs now operating in Australia and Indonesia, we are moving with pace toward global registration. The expansion to Moderate DFI materially broadens the patient population and the market we are targeting. This is a program that is advancing rapidly, and the commercial opportunity is growing with it."

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

[3] Diabetes Australia. Facts and figures. Available at: diabetesaustralia.com.au
[4] Zhang Y, Cramb SM, McPhail SM, et al. The incidence of and risk factors for hospitalisations and amputations for people with diabetes-related foot ulcers in Queensland, 2011–19. *Medical Journal of Australia*. 2025. doi: 10.5694/mja2.52703

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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.

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 Initiatives 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.