

Phase II Clinical Trial Receives Additional Approval for Treating Diabetic Patients with RECCE® 327 Topical Gel

Highlights:

- Human Research Ethics Committee (HREC) approval received to allow up to 20 additional patients access to RECCE® 327 Topical Gel (R327G) treatment under existing open-label study protocol
- Program driven to allow access to R327G for treatment of Diabetic Foot Infections (DFI) following the recently released positive Phase II clinical trial data of R327G for Acute Bacterial Skin and Skin-Structure Infections (ABSSSI), including Diabetic Foot Ulcer Infections
- Access focused upon Diabetic Foot Ulcer Infection patients given the unmet medical need as ~40% ulcer recurrence in diabetics within first year of an ulcer healing
- The study will start now and run in parallel to Registrational Phase 3 in Indonesia (gateway to ASEAN) for DFI and planned Registrational Phase 3 for ABSSSI in Australia on track for H2 2025

Sydney Australia, 22 April 2025: Recce Pharmaceuticals Limited (ASX:RCE, FSE:R9Q), (Recce or the Company), a leading developer of a New Class of Synthetic Anti-infectives, is pleased to announce it has received Human Research Ethics Approval (HREC) approval to build upon its Phase II Clinical Trial for the treatment of Diabetic Foot Infections (DFI) by enrolling up to 20 additional patients with DFI, to provide access to R327G in this open-label study.

The use of R327G under this protocol follows strong interest by investigators encouraged by the highly promising results of the recently released Phase II data, where R327G demonstrated after 7-days of treatment, 86% of patients treated had a successful clinical response (the primary endpoint also used by FDA) and at 14-days of treatment, >90% of patients achieved a primary efficacy endpoint.



The investigators of the trial have expressed confidence in R327G as a safe and well tolerated therapeutic, particularly in difficult-to-treat infections such as DFIs, where standard treatments often fall short. Using a gel avoids using systemic (oral & IV) antibiotics with their associated adverse effects. This study offers an opportunity to further strengthen the clinical profile of R327G while addressing the urgent needs of patients currently lacking effective treatment options.

The study will start now and run in parallel with Recce's Indonesian Phase 3 trial, which remains on track to commence shortly. This program does not impact the initiation timeline of the Registrational Phase 3 DFI study in Indonesia or the planned Registrational Phase 3 for ABSSSI in Australia and is designed to run in-parallel and is expected to generate additional data to support future regulatory submissions. The study will be conducted by Barwon Health further supporting the Company's clinical momentum in Australia.

Chief Executive Officer James Graham said "This approval allows us to build upon the strong clinical results of R327G and continue demonstrating its potential as a differentiated treatment for DFIs. We are pleased to continue to provide access to R327G to diabetic patients in need, and to further build out our data portfolio alongside our Phase 3 programs in both Australia and Indonesia."

Chief Medical Advisor and Non-Executive Director Dr Alan W Dunton said "It is important to provide additional therapeutic options to diabetic patients with infections. Recce's compound has an optimal profile as a localised therapeutic for patients, in contrast to treatment with IV and oral antibiotics which, are often not effective and are accompanied with unwanted side effects such as diarrhea and gastrointestinal distress."

The recurrence rate of diabetic foot infection within 1 year after healing is 40%, the recurrence rate is 60% within 3 years and 65% within 5 years.¹ The risk of a person with diabetes developing a foot infection has been estimated to be between 34%² and 50%³. These infections can lead to sepsis, gangrene, amputation, and death.³

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

¹ <https://pmc.ncbi.nlm.nih.gov/articles/PMC10088840/#iwj14017-bib-0004>

² <https://www.ncbi.nlm.nih.gov/books/NBK409609/>

³ <https://www.uptodate.com/contents/evaluation-of-the-diabetic-foot>

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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 (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.

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