

ASX Announcement

Independent Data Monitoring Committee to Review Phase 3 Clinical Trial Data of Recce's Topical Gel for Diabetic Foot Ulcer Infections

Highlights:

- Review of the blinded data indicates strong efficacy across the study population
- RECCE® 327 Gel (R327G) continues to demonstrate an excellent safety and tolerability profile
- Independent Data Monitoring Committee (DMC) will review unblinded data from Phase 3 diabetic foot infection trial in Indonesia and prepare recommendations
- DMC recommendations will be available following the conclusion of its meeting, expected to occur as soon as mid-November 2026
- Patient recruitment and dosing remain ongoing during this process

SYDNEY Australia, 20 October 2026: Recce Pharmaceuticals Ltd (**ASX:RCE, FSE:R9Q**) (the **Company** or **Recce**), a leading developer of a new class of synthetic Anti-infectives, advises that a review of blinded data of its current Phase III trial undertaken by clinical experts and a statistician indicates strong efficacy along with a very positive safety profile. A data set of 75 patients has now been formally submitted to the Data Monitoring Committee (**DMC**) who will unblind the data (create separate data sets of patients who received R327G or placebo gel) for its Phase 3 clinical trial in Indonesia. The DMC will provide its recommendations to the Company following the conclusion of its meeting expected as soon as mid-November.

The study is a pivotal, double-blind, placebo-controlled Phase 3 clinical trial evaluating the efficacy and safety of RECCE® 327 Gel (R327G) in the treatment of diabetic foot infections (DFI) in Indonesia. Currently, 90 patients are enrolled with an existing enrolment rate of 4.5 patients per week.

An important component of any pivotal clinical study conducted in accordance with Good Clinical Practice (**GCP**) is oversight by an independent Data Monitoring Committee. The DMC's role is to periodically review accumulating clinical trial data, including efficacy and safety outcomes, and provide recommendations regarding the ongoing conduct of the study.

The independent DMC will unblind (meaning they will be granted access to the treatment allocations that reveal which patients received R327G versus the placebo gel) and review efficacy and safety



ASX: RCE, FSE: R9Q

Head Office: Level 15, 1 Farrer Place, Governor Macquarie Tower, SYDNEY NSW 2000 **T** +61 (2) 9000 1907

R&D Centre - Perth: Suite 10, 3 Brodie Hall Drive, Technology Park, BENTLEY WA 6102 **T** +61 (8) 9362 9860

Washington Office: 1717 Pennsylvania Avenue NW, Suite 1025, WASHINGTON DC 20006 USA

data. While the DMC performs this ad-hoc review, the Company, clinical investigators and patients will remain fully blinded (meaning they will not know which patients have received R327G or placebo treatment) to the treatment groups to protect the scientific integrity of the trial. This enables the committee to assess patient outcomes by treatment group and determine appropriate recommendations regarding the progression of the study. The study will continue during the DMC review process. This DMC process is built into the clinical trial protocol and typically part of any pivotal GCP protocol.

A recent independent review of the blinded data by Australian and international infectious disease specialists, clinical investigators, and biostatistical experts was conducted following completion of patient follow-up. The review demonstrated encouraging clinical outcomes across the study population, with a high proportion of patients experiencing either resolution or improvement of infection. In addition, the blinded safety data continue to indicate that R327G is safe and well tolerated.

Following its meeting, the DMC will submit its findings and recommendations to the Company. In accordance with standard clinical protocols, the DMC's recommendations may include:

- advising the Company to progress towards regulatory submission and potential product registration if supported by the safety and efficacy data;
- continuing the trial unchanged without modifications;
- amending the trial protocol (such as modifying sample sizes, dosing schedules, or patient selection criteria) to optimise patient safety or study validity; or
- pausing or halting the trial due to safety concerns or clear futility.

Recce will provide a market update once it has received and evaluated the DMC's formal recommendations, in accordance with its continuous disclosure obligations.

James Graham, Chief Executive Officer said "The forthcoming DMC review represents an important milestone in our Phase 3 diabetic foot infection program. While Recce remains blinded to treatment allocation, the overall efficacy and safety profile observed to date is encouraging. We look forward to receiving the independent DMC assessment and will keep shareholders informed of any material developments. DFI represents a significant global healthcare challenge and an area of substantial unmet medical need where R327G is anticipated to become the standard of care for the treatment of Diabetic Foot Ulcer Infections".

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

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.