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Patient Dosing and Multiple Sites Activated in Registrational Phase 3 Clinical Trial for Diabetic Foot Infections in Indonesia

Highlights:

- **Patient dosing is underway for Registrational Phase 3 Clinical Trial for Diabetic Foot Infections (DFI), with five (5) clinical study sites now activated across one of the world's largest DFI patient populations**
- **Interim analysis results expected in Q1 2026; upon receiving a positive result confirmed by the Independent Data Management Committee, a submission for accelerated approval will be pursued with a potential commercial launch in 2026**
- **Significant market opportunity with prevalence of diabetes in Indonesia estimated at 20.9 million adults, approximately 11.3% of the nation's adult population, more than 1 in every 10 adults**

SYDNEY Australia, 25 September 2025: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company** or **Recce**), a leading developer of a new class of Synthetic Anti-infectives, is pleased to announce that patient dosing is underway for its Registrational Phase 3 clinical trial in Indonesia with clinical trial sites now activated and study on track for Q1 2026 readout.

With these sites active, patient dosing is underway with a target enrolment of up to 310 DFI patients randomised to receive either RECCE® 327 Topical Gel (R327G) or placebo. The trial's primary objective is to assess the clinical response of the DFI according to the Lipsky Scale. Recognised by the FDA, the Lipsky Scale is a valid and reliable method for evaluating the treatment outcomes for diabetic foot infections. Secondary endpoints include a DFI total wound score and safety of R327G including clinical observations and adverse events.

Based on the approved statistical plan the Company's Registrational Phase 3 Study for DFI expects to meet a highly statistically significant positive endpoint after dosing approximately 155 patients. The Indonesian Drug and Food Regulatory Authority (Badan POM or BPOM) approved protocol has a built-in interim analysis as well as Expedited Regulatory Review status. An independent data management committee aims to complete this analysis and make recommendations within Q1 2026.

James Graham, Chief Executive Officer of Recce Pharmaceuticals said "Thanks to the positive engagements with Indonesia's Food and Drug Authority (Badan POM), we are pleased to have

successfully activated multiple leading clinical sites across Indonesia and the Registrational Phase 3 DFI patient dosing is underway. With R327G positioned as the first potential treatment for DFI, we see ourselves well positioned to meet the infectious disease challenges among the global rise in diabetes."

Overview of Indonesian Opportunity

- **Over 20.9 million adults** in Indonesia are **living with diabetes**[1] representing approximately 11.3% of the nation's adult population, or more than 1 in every 10 adults **- ranking 5th in the world for diabetes prevalence.**
- This figure is among the highest rates in Southeast Asia and is nearly equivalent to the entire population of Australia, underscoring both the scale of the disease burden and the urgent need for new treatment solutions.
- **High need for innovative broad-spectrum therapies** to address diabetes-related infections (e.g. DFI, urinary tract infections, surgical site infections).
- **New regulations in Indonesia have increased regulatory approval times** for new drugs and made it cheaper and easier for foreign pharmaceutical companies to conduct clinical trials.
- Approximately **60% of all diabetic foot ulcers develop infection**, which can progress to sepsis, gangrene, amputation, and even death[2].
- Recce's Registrational Phase 3 Clinical Trial of R327G is one of the **largest DFI studies in the world.**

First patient dosing follows approvals from Indonesia's Food and Drug Authority (Badan POM) and Human Research Ethics Committee (HREC), the trial is also bilaterally supported by both the Indonesian and Australian governments and local Indonesian biomedical collaborator PT Etana.

R327G has demonstrated clinical efficacy, curing infections in patients with acute bacterial skin and skin structure infections which includes DFI patients in a Phase II trial as well as other smaller patient efficacy studies. The drug was very well tolerated with no signal of any serious safety concerns. Based on this successful Phase II study, the Phase 3 trial was designed with changes at a minimum in order to replicate the Phase II findings.

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

[1] https://idf.org/our-network/regions-and-members/western-pacific/members/indonesia/
[2] Armstrong DG, Tan TW, Boulton AJM, Bus SA. Diabetic Foot Ulcers: A Review. JAMA. 2023 Jul 3;330(1):62-75.

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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.

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