

## ASX Announcement

# Positive Outcome of Routine Regulatory Inspection of Indonesian Phase 3 Clinical Trial Site

### Highlights:

- **Comprehensive regulatory inspection successfully completed for Phase 3 clinical trial site for the treatment of Diabetic Foot Infections**
- **Indonesian National Agency of Drug and Food Control (Badan POM) has not requested any changes to the ongoing clinical trial**
- **Phase 3 clinical trial patient dosing continues across five sites with interim data analysis to be conducted at 155 patients completed**

**Sydney Australia, 21 April 2026:** Recce Pharmaceuticals Ltd (**ASX:RCE**) (**Recce** or the **Company**), a leading developer of synthetic anti-infectives, is pleased to announce that the Indonesian National Agency of Drug and Food Control (Badan POM or BPOM) has successfully completed a comprehensive routine regulatory inspection of a Phase 3 (Trial Name: R327-G301) clinical trial site in Indonesia.

The inspection formed part of BPOM's standard regulatory oversight of clinical studies and included a comprehensive review of trial conduct, site processes, data integrity, and compliance with applicable Good Clinical Practice (GCP) standards.

Recce is pleased to report that the inspection was completed with no findings noted that prevent the study from continuing. The outcome reflects the high quality of the Company's clinical operations in Indonesia and adherence to regulatory requirements.

The BPOM inspection represents a critical de-risking milestone for Recce's registrational Phase 3 clinical trial in Indonesia for the treatment of diabetic foot infections and supports the pathway toward regulatory approval and commercialisation in Indonesia followed by other ASEAN countries. Patient dosing is progressing, with the study on track to produce interim data expected at 155 patients.

Regulatory approval in Indonesia is anticipated in CY26 and represents a compelling near-term commercial opportunity. With diabetes impacting 11% of the Indonesian population (over 20.9 million adults), ranking fifth in the world for diabetes prevalence<sup>i</sup>, this positions Recce at the gateway to the broader Asia-Pacific market representing a market opportunity of approximately US\$1.5 billion<sup>ii</sup>.



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**Chief Executive Officer, James Graham, said:** “We are pleased with the outcome of BPOM's inspection, which reinforces the high standards of our clinical program maintained by our teams and partners working throughout Indonesia. This result provides further confidence in the integrity of our data collection and the robustness of our development pathway as we progress towards potential regulatory approval. The Company looks forward to continuing its engagement with BPOM and advancing its clinical programs in the region.”

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.

<sup>i</sup> <https://diabetesatlas.org/data-by-location/country/indonesia/>

<sup>ii</sup> Business Market Insights, Asia Pacific Diabetic Foot Ulcer Market, 2021