ASX Announcement

Recce Pharmaceuticals
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ACN 124 849 065

Ethics Approval Received in Indonesia to Commence Dosing in a Registrational Phase 3 Clinical Trial of RECCE® 327 Topical Gel in Diabetic Foot Infections

Highlights:

- **Human Research Ethics Committee approval received for Registrational Phase 3 Clinical Trial for RECCE® 327 Topical Gel in patients with Diabetic Foot Infections**
- **Registrational Phase 3 clinical trial for Diabetic Foot infections to be conducted across Indonesia, one of the world's largest diabetes patient populations**
- **Phase 3 read-out and regulatory submission expected in late 2025 with potential approval and commercial launch in H1 2026**
- **Bilateral initiative supported by Australian and Indonesian Governments with clinical support from leading Indonesian biopharmaceutical company PT Etana Biotechnologies**

Sydney Australia, 11 November 2024: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**), (the **Company**), the Company developing a New Class of Synthetic Anti-Infectives, is pleased to announce it has received Human Research Ethics Committee approval to commence a Registrational Phase 3 clinical trial of RECCE® 327 as a topical gel (R327G) for the treatment of diabetic foot infections (DFI). Ethics approval signifies that Recce has met the safety and efficacy testing required to proceed with this large-scale late-stage clinical trial.

The trial will be conducted as a double-blinded, placebo-controlled study evaluating R327G for the treatment of DFIs and is on track to begin mid-December and aims to enrol up to 300 patients (200 to receive R327G and 100 to receive placebo). The trial will run for approximately 12 months, with an expected read-out in late 2025 and expected regulatory approval and commercial launch in H1 CY26.

The study is made possible thanks to the significant support of key Indonesian stakeholders, including the Indonesian Ministry of Health, Badan POM, PT Etana Biotechnologies, and the

Australian Government, accelerating R327G's path to commercialisation. The study will cost Recce around US$2M before further subsiding by the Australian government's 43.5% R&D rebate scheme under the Company's Advanced Overseas Advanced Finding status with AusIndustry. All intellectual property is that of Recce.

Indonesia's clinical trial approval process involves two key steps, including ethics approval (now approved) and BPOM (expected to imminently follow). Successfully completing this trial would enable Recce to replicate regulatory approval for R327G across the broader ASEAN region, including Malaysia, the Philippines, Singapore, and Thailand, as a treatment for DFIs, addressing a critical unmet need for new therapeutics in countries facing increasing rates of antimicrobial resistance and infectious diseases.

The trial will be initially conducted at PT Siloam International Hospitals, the largest private hospital network that provides health service facilities in hospitals and clinics in various cities across Indonesia. This approval to commence dosing in a registrational Phase 3 DFI clinical trial comes off the back of 100% patient response rate in a present Acute Bacterial Skin and Skin Structure Infections (ABSSSI) study in Australia, showing all patient infections were cured/improved with R327G treatment.

The risk of a person with diabetes developing a foot ulcer has been estimated to be as high as 34%[1]. Approximately 50% of all diabetic foot ulcers develop infection, which can lead to sepsis, gangrene, amputation, and death[2]. The DFI treatment market is estimated to be worth ~US$5.2 billion[3]. Initially targeting Indonesian market is anticipated to be worth ~US$189m where Diabetes each year impacts 11% of the population[4]. Indonesian approvals would provide access to the broader Asia Pacific market worth ~US$1.0 billion per year[5].

Recce Pharmaceuticals Chief Executive Officer, James Graham, said: "Today marks the achievement of a landmark milestone in Recce's clinical program development. We are thankful for the unparalleled support from our Indonesian partners in bringing our innovative anti-infective therapy to patients in need. This welcomed approval signals the beginning of our clinical programs in Indonesia and the broader ASEAN region, bringing Recce one step closer to commercialisation. We look forward to evaluating R327G in our first Phase 3 trial."

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

[1] *The Diabetic Foot NCBI*
[2] *Up tp Date Evaluation of the diabetic foot*
[3] *Grand View Research, Diabetic Foot Ulcer Treatment Market Size, 2023*
[4] *Diabetes Atlas, International Diabetic Federation and Prof EM Yunir, Faculty of Medicines, University of Indonesia.*
[5] *Business Market Insights, Asia Pacific Diabetic Foot Ulcer Market, 2021*

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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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