ASX Announcement

Recce Receives Approval from Indonesia's Drug and Food Authority for Registrational Phase 3 Clinical Trial of RECCE® 327 Topical Gel in Diabetic Foot Infections

Highlights:

- **Registrational Phase 3 clinical trial for Diabetic Foot infections to be conducted across Indonesia, one of the world's largest diabetes patient populations**
- **Awarded expedited regulatory review status in Indonesia to fast-track progression of Phase 3 trial; bringing forward commercial opportunities in ASEAN region**

Sydney Australia, 9 December 2024: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**), (**Recce** or the **Company**), the Company developing a New Class of Synthetic Anti-Infectives, is pleased to announce it has received approval from the Indonesian Drug and Food Regulatory Authority, Badan POM, to initiate its Registrational Phase 3 clinical trial assessing RECCE® 327 as a topical gel (R327G) for the treatment of diabetic foot infections (DFIs).

This significant milestone follows the recent human ethics committee approval to commence patient dosing, underscoring Recce's clinical research's alignment with regulatory and ethical standards within Indonesia. With both approvals now secured, the Company remains on track to commence the registrational Phase 3 clinical trial this quarter.

These advancements are not only significant for the Company's growth but also contribute positively to Indonesia's healthcare landscape by introducing potential novel treatments for infectious diseases, aligning with Recce's commitment to addressing critical health challenges on an international scale.

Commenting on the approval, the **Chairperson of the Indonesian Food and Drug Authority (BPOM), Dr. Taruna Ikrar**, said: "The approval of Recce Pharmaceuticals' Phase 3 clinical trial is an important advancement in expanding treatment options for diabetic foot infections in Indonesia. BPOM is committed to fostering the timely development of innovative therapies to address urgent health challenges. This collaboration reflects Indonesia's mission to enhance

healthcare outcomes for its population, and we are eager to see the trial's impact on patients requiring effective, novel anti-infective treatments."

With over 19.5 million adults living with diabetes in Indonesia[1], the need for innovative therapies to address diabetes-related infections, such as foot infections, urinary tract infections, and surgical site infections, is urgent. As a Registrational Phase 3 clinical trial for DFIs, this is one of the largest DFI studies in the world[2] and the first of its kind across Indonesia.

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.

On a local front, with the Phase 2 Acute Bacterial Skin and Skin Structure Infections (ABSSSI) clinical trial in the final stages and on track to finish this calendar year, Recce is expected to initiate a Phase 3 registrational study of R327G in Australia in H1 2025, with a parallel program across the ASEAN focused initially on DFIs allowing an expansive international strategy, bringing near-term revenue opportunities of ASEAN to the forefront.

Recce Pharmaceuticals Chief Executive Officer, James Graham said: "The approval from the Indonesian National Drug and Food Authority to initiate this pivotal Phase 3 trial in Recce's clinical development is a significant achievement, bringing Recce closer to commercialisation and profitability. We also acknowledge the support of Investment NSW, Austrade, and the Australian Embassy team in Jakarta who played an important role in helping with the approval process. We look forward to evaluating R327G in our first Phase 3 trial."

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] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8351150/

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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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