ASX Announcement

Positive Phase II Data from Clinical Trial of RECCE® 327 Gel Supports Accelerated Commercialisation Pathway

Highlights:

- **Successful Phase II clinical trial assessing efficacy and safety of RECCE® 327 topical gel (R327G) in patients with Acute Bacterial Skin and Skin Structure Infections (ABSSSI) including patients with Diabetic Foot Infections (DFI)**
- **Study objectives exceeded with a 93% primary efficacy endpoint achieved for R327G over 14 days treatment**
- **Phase II data confirms approach for the Approved Registrational Phase 3 DFI Indonesian Study, where efficacy can be confirmed earlier in trial through interim analysis and read out expected in 2025**
- **Additionally, study to progress to Registrational Phase 3 in ABSSSI/DFI in Australia**
- **Trial results continue to reinforce the unprecedented efficacy of Recce's synthetic technology, now in late stage clinical trials, facilitated by an innovative regulatory strategy, supporting an accelerated commercialisation pathway into 2026**

Sydney Australia, 17 February 2025: 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 positive patient data analysis in its Phase II clinical trial of RECCE® 327 Topical Gel (R327G) for the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI).

Results

The Phase II clinical trial successfully demonstrated R327G achieving a 93% primary efficacy endpoint over 14-days, meeting all study endpoints.

After 7-days of treatment, 86% of patients (25 out of 29) treated with R327G had a successful clinical response. At 14-days of treatment, 93% of patients (27 out of 29) achieved a primary efficacy endpoint. R327G demonstrated to be safe and well tolerated, with no serious adverse

events (SAE) reported, achieving all endpoints.

Study Outcome*	To evaluate the efficacy of RECCE®327 topical gel on ABSSSI
Assessment method	Lipsky Scale/Bates Jensen Wound Assessment Tool
Endpoint met	**Yes**

**https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=387997&isReview=true*

The study enrolled 30 patients, with 29 included in the final data analysis. One patient was withdrawn due to pre-existing pain at the wound site that was deemed unrelated to R327G.

Positive Implications for Phase 3 Registrational Trial

Driven by the high response rates in this study, experts have determined the Company's current Registrational Phase 3 Study for Diabetic Foot Infections can meet a highly statistically significant positive endpoint after completing approximately 100 patients (compared to study baseline of 300 patients). The Indonesian Drug and Food Regulatory Authority (Badan POM) approved protocol has a built-in interim analysis. The Company anticipates completing this data set by end-of-year.

Trial Overview and Outcomes

This Phase II study achieved all primary and secondary endpoints as an open-label clinical trial evaluating the safety and tolerability, efficacy, and plasma pharmacokinetics of R327G when applied directly to the infected area. The trial included both men and women with a minimum age of 18 years old and no maximum age limit. The data received from this trial aligns with the US Food and Drug Administration's (FDA) increased demand for novel broad-spectrum antibiotics (such as R327G) to address antimicrobial resistance (AMR). ABSSSIs are a significant healthcare concern, encompassing indications such as Diabetic Foot Infections (DFI), necrotizing fasciitis, and post-operative wound infections. There are no ABSSSI placebo-controlled studies as international regulators deem it unethical to withhold appropriate treatment of patient infections.

The trial used FDA accepted diagnosis tools for assessing the severity of patient wounds, including the Lipsky Clinical Resolution of Infection Scale and/or the Bates Jensen Wound Assessment tool. The study's investigators used these methods to evaluate patient wound healing, and subsequently rated patients as either cured or improved. Both assessments (cured/improved) demonstrate that wound healing has been observed, with cured meaning a full clinical response and improved demonstrating partial wound healing with the potential of a cure beyond the 14-day timeframe.

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James Graham, CEO of Recce Pharmaceuticals said: "These impressive results underscore the potential of our topical gel to meet critical unmet medical needs in infection treatment. As we advance towards registrational Phase 3 trials in Indonesia, and Australia, we are encouraged by the rapid efficacy and strong safety outcomes demonstrated in this study. The global ABSSSI treatment market is a substantial commercial opportunity, valued at $7.3B USD in 2018 and expected to reach $26B USD by 2032, at a CAGR of 9.5% between 2019 and 2032. Going forward with our clinical programs, this gives us great confidence in addressing ABSSSI."

Dr Alan Dunton, Director & Chief Medical Advisor of Recce Pharmaceuticals, added: "Our robust dataset, from pre-clinical, clinical and TGA special access scheme use cases, gives us confidence in the potential of our topical gel. These results reflect the broad-spectrum nature and rapid onset of effect of R327G, which positions us well for the upcoming Phase 3 trials in Indonesia and Australia. Importantly, Recce has also demonstrated that its R327 anti-infective compounds are effective against diverse species of bacteria, including *in-vitro* against over 500 clinical isolates, many previously considered as drug-resistant."

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

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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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