ASX Announcement

Recce Pharmaceuticals
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ACN 124 849 065

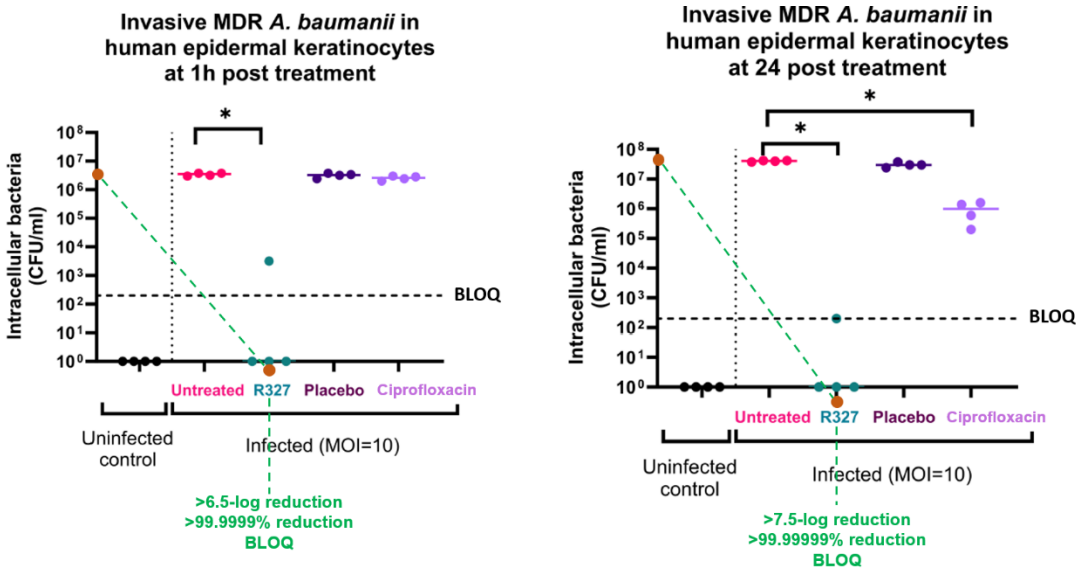
Positive Efficacy Data from Murdoch Children's Research Institute in Study against WHO Priority Pathogen *Acinetobacter baumannii*

Highlights:

- **RECCE® 327 (R327) demonstrates significant bactericidal activity against 'superbug' *Acinetobacter baumannii* (*A. baumannii*) in adult human epidermal 'skin' cells: 99.99999% log reduction (>7.5 log reduction) observed**
- **Urinary tract infections, ventilator-associated pneumonia, central line-associated bloodstream infections, persistent wound infections and meningitis are the most common clinical manifestations that arise from *A. baumannii***
- **Supports present Phase II Acute Bacterial Skin and Skin Structure Infection (ABSSSI) trials as *A. baumannii* infections are notoriously difficult to treat, especially in their drug resistant 'superbug' form as in this study**

Sydney Australia, 8 July 2024: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**), (the **Company**), the Company developing a New Class of Synthetic Anti-Infectives, is pleased to report promising results from its latest study on the efficacy of RECCE® 327 (R327) against multidrug-resistant (MDR) World Health Organization (WHO) priority pathogen *Acinetobacter baumannii* (*A. baumannii*). The study was conducted at Recce's Anti-Infective Research (AIR) unit within Murdoch Children's Research Institute.

The study demonstrated R327's bactericidal activity when compared to placebo and ciprofloxacin in just 1-hour post treatment and at 24-hours post treatment in primary human epidermal keratinocytes (skin cells) infected with *A. baumannii*.



BLOQ – Below Limit of Quantification

Key Findings from the study include:

- **1-hour Post-treatment Efficacy:** Within the first hour post-treatment of invasive (intracellular) Multidrug-Resistant *A. baumannii* in primary human epidermal keratinocytes, R327 achieved a >6.5 log reduction, rendering the bacteria below the limit of quantification (BLOQ). This demonstrates the rapid and effective bactericidal action of R327. In contrast, ciprofloxacin did not show any reduction in intracellular bacterial burden at this early timepoint.
- **24-hour Sustained Efficacy:** R327 maintained its efficacy at >6.5 log or >99.9999% reduction in intracellular bacteria even after 24 hours, a critical factor in infection management. In comparison, ciprofloxacin treatment only resulted in ~1 log reduction in bacterial numbers over the same period.

The WHO has listed *A. baumannii* as one of the top priority pathogens due to its high levels of resistance to multiple antibiotics. *A. baumannii* is now a significant global health threat, known for causing severe infections, both in hospital settings and within the community.

Prevalent infections from *A. baumannii* include persistent wound infections, central line-associated bloodstream infections (BSIs), catheter-associated Urinary Tract Infections (UTIs), ventilator-associated pneumonia (VAP), and meningitis. Infections caused by MDR *A. baumannii* can lead to prolonged hospital stays, increased healthcare costs, and high mortality rates, with some studies reporting mortality rates as high as 50% in critically ill patients.

The results from this study build upon successful Phase II Diabetic Foot Ulcer Infection data including recent completion and data from the Phase I/II rapid infusion clinical trial, with R327 demonstrating safety and efficacy against *E. coli* in *ex vivo* testing. The demonstrated efficacy against MDR *A. baumannii* further builds out the efficacy profile of R327 against UTI-causing pathogens and will support the initiation of a Phase II trial in patients with UTI/Urosepsis.

James Graham, CEO of Recce Pharmaceuticals, commented, “These outstanding results highlight the potent efficacy of R327 in combating MDR bacteria, a significant global health challenge. The ability of R327 to achieve such substantial reductions in bacterial load and maintain its effectiveness over 24 hours is a testament to its potential as a leading anti-infective treatment. We are excited about these findings and their implications for the future of infection management.”

Dr. Sohinee Sarkar, a leading researcher at Murdoch Children’s Research Institute, added, “The significant bactericidal activity observed with R327, particularly its ability to reduce bacterial presence to BLOQ, marks a major advancement in our fight against resistant pathogens. The sustained efficacy of R327 compared to ciprofloxacin underscores its potential as a superior treatment option. These results are promising and pave the way for further development and application of R327 in clinical settings.”

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 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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