ASX Announcement

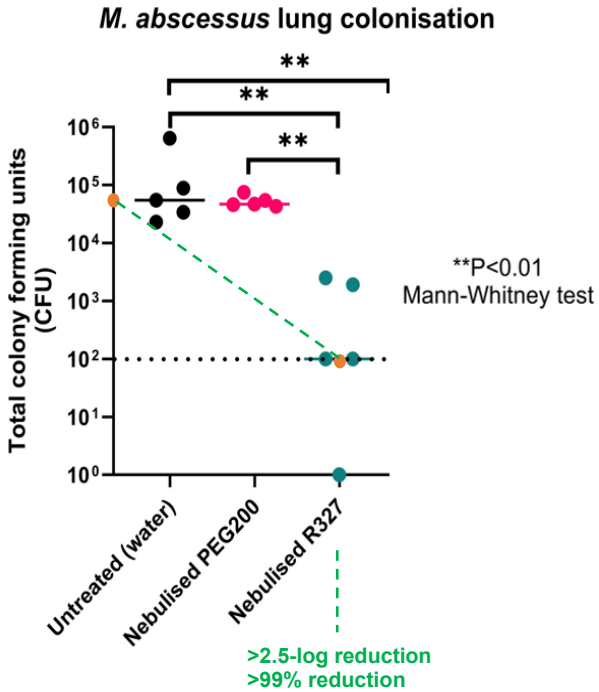
Recce Pharmaceuticals
recce.com.au
ACN 124 849 065

Positive Efficacy Data from Murdoch Children's Research Institute in Pilot Study for Lung Infections

Highlights:

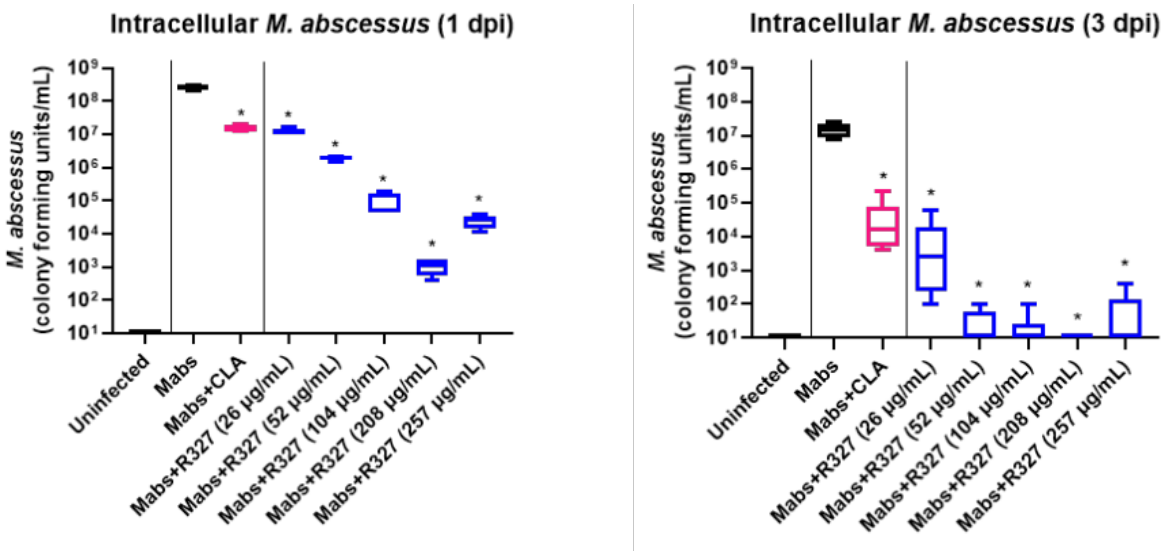
- **RECCE® 327 (R327) demonstrates efficacy in treating *Mycobacterium abscessus* lung infections using recently developed nebuliser delivery method: >99% log reduction (>2.5 log reduction) observed**
- **Nebuliser delivery method of R327 allows company to explore respiratory infectious disease opportunities**
- **Infections due to *Mycobacterium abscessus* are a major cause of mortality and morbidity in cystic fibrosis patients**
- **R327 evaluated for potential use to treat Ventilator-associated pneumonia (VAP) and hospital-acquired pneumonia (HAP)**

Sydney Australia, 9 May 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 pilot study on the efficacy of nebulised RECCE® 327 (R327) for treating lung infections in a mouse model. The study was conducted at Recce's Anti-Infective Research (AIR) unit within Murdoch Children's Research Institute.



The pilot study demonstrated a substantial reduction in *Mycobacterium abscessus* (*M. abscessus*) colonisation in both lungs of mice treated with nebulised R327. Notably, nebulised R327 significantly decreased *M. abscessus* bacterial colonisation, and the mice maintained a stable body weight throughout the study period, indicating the treatment's safety and tolerability. This pilot study represents an important step towards exploring new methods of administration across a broad range of therapeutic indications, which pose an increasing threat in healthcare settings globally.

The Company has previously conducted studies investigating the effect of R327 against *M. abscessus* infecting stem cell-derived macrophages, where R327 demonstrated a dose-dependent killing of intracellular *M. abscessus* with no toxicity observed against treated (physiologically relevant) human macrophages, or in intranasally-infected mice. Furthermore, R327 was shown to be superior to the positive control Clarithromycin (CLA as seen below), one of the rare antibacterial agents used in the 1990s with some success and became the treatment of choice[1].



dpi – days post infection
Mabs – M. abscessus

dpi – days post infection
Mabs – M. abscessus

Infections due to *Mycobacterium abscessus* are a major cause of mortality and morbidity in cystic fibrosis (CF) patients[2]. Current treatment guidelines recommend a prolonged and intense combination therapy consisting of several antibiotic agents with significant adverse effects[3].

James Graham, CEO of Recce Pharmaceuticals, commented, "These results represent a significant milestone in the development of nebulised treatments for lung infections. The ability of R327 to significantly decrease bacterial infections in the lungs without adverse effects on the host is a testament to its potential as a safe and effective treatment option."

Ventilator-associated pneumonia (VAP) is a major concern in healthcare settings, with occurrences in 9-27% of mechanically ventilated patients[4]. Given the high incidence and severity of VAP, R327's results suggest it could fill a critical gap in the treatment of this and similar infections. Hospital-acquired pneumonia (HAP) is one of the most common nosocomial infections and is associated with significant clinical and economic burdens, such as long-term hospitalisation, high medical costs, and increased morbidity and mortality[5].

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5192163/
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9431180/
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9431180/
[4] https://ccforum.biomedcentral.com/articles/10.1186/cc13775#:~:text=VAP%20is%20estimated%20to%20occur,4%5D%2C%20%5B5%5D
[5] https://bmcpulmmed.biomedcentral.com/articles/10.1186/s12890-021-01816-9

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Dr. Sohinee Sarkar, lead researcher at Recce's AIR unit, added, "The results are very promising and pave the way for future clinical applications. This could be particularly transformative for patients suffering from VAP and HAP, conditions that significantly increase morbidity and mortality rates in intensive care units."

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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