ASX Announcement

Recce Pharmaceuticals
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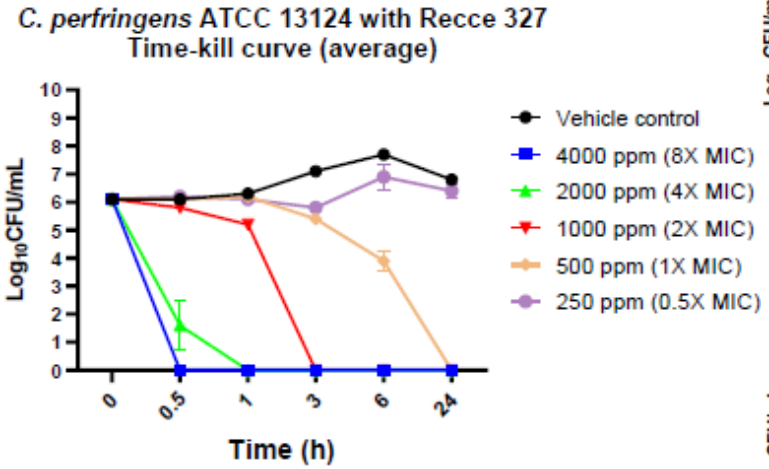
RECCE® 327 Demonstrates Outstanding Efficacy Against Necrotizing Fasciitis 'Flesh-Eating' Bacteria

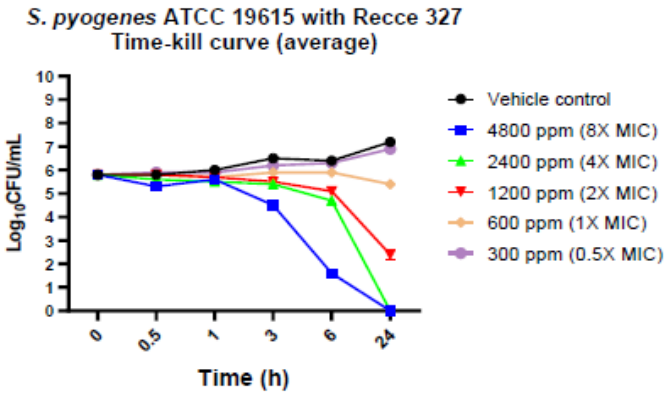
Highlights

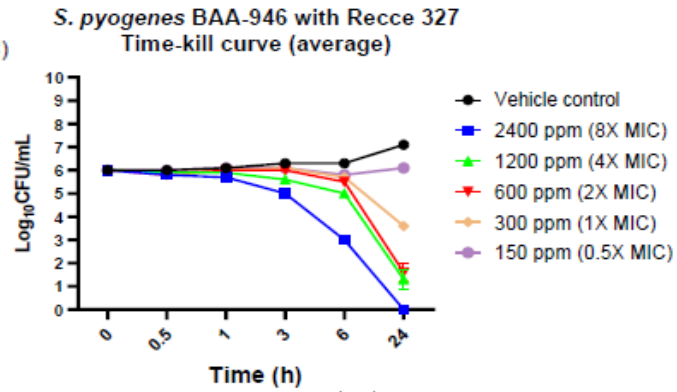
- **RECCE® 327 (R327) shown to reduce deadly 'flesh-eating' bacterial count Below Limit of Quantification (BLOQ) within 24 hours, at varying concentrations**
- **R327 BLOQ efficacy as early as 30 minutes in *C. perfringens* – a leading bacterial cause of myonecrosis (gas gangrene)[1]**
- **99.9% (3-log) bacterial reduction achieved in all bacteria tested, at various concentrations**
- **Data demonstrates R327's potential against bacterial infections that thrive in nil/low oxygen environments i.e. diabetic wounds/ulcers infections**

Sydney Australia, 19 July 2021: Recce Pharmaceuticals Ltd (**ASX:RCE**) (**FSE:R9Q**) (**Company**), the Company developing New Classes of Synthetic Anti-infectives, is pleased to announce positive efficacy of RECCE® 327 (R327) against *Clostridium perfringens (C. perfringens)* and *Streptococcus pyogenes (S. pyogenes)*, two main strains of bacteria associated with necrotizing fasciitis, also known as 'flesh-eating' disease – a life-threatening bacterial infection with a mortality rate of up to 80%[2].

The study was conducted by an independent contract research organisation to evaluate the *in vitro* bactericidal properties of R327 against *C. perfringens* and *S. pyogenes*. Doses of R327 up to 4,800 parts per million (ppm) were tested, covering concentrations from 0.5x to 8x the minimum inhibitory concentration (MIC). The strains tested were: *S. pyogenes* – a susceptible strain; *S. pyogenes* – an erythromycin-resistant strain; and *C. perfringens*.







Time-kill summary, Time (hrs) with a 99.9% (3-log reduction) reduced bacterial count

Compound	Test Strain	Test Concentration (ppm)	Time of 3-log reduction (hrs)	BLOQ* (24hr count)
R327	*S. pyogenes* - susceptible strain	4800 (8x MIC)	6 to 24	✓
		2400 (4x MIC)	24	✓
		1200 (2x MIC)	24	-
	S. pyogenes - erythromycin-resistant strain	2400 (8x MIC)	6 to 24	✓
		1200 (4x MIC)	24	-
		600 (2x MIC)	24	-
	C. perfringens	4000 (8x MIC)	0.5 to 24	✓
		2000 (4x MIC)	0.5 to 24	✓
		1000 (2x MIC)	3 to 24	✓
		500 (1x MIC)	24	✓

Time of the 3-log$_{10}$ reduction is the time point in which CFU counts at the respective test condition is reduced relative to the initial CFU counts by ≥3-log$_{10}$. The initial CFU counts are at the start, time 0, of the assay.
**BLOQ – Below Limit of Quantification*

The R327 concentrations and time points that yielded a bactericidal effect are as follows:

- At hours 6 and 24, **R327 showed bactericidal activity** against the *S. pyogenes* susceptible strain at 1,200 ppm, 2,400 ppm and 4,800 ppm, while also **achieving a BLOQ** at the 24 hour count with concentrations of **2,400 ppm and 4,800 ppm** (4X – 8X MIC).
- In addition to the susceptible strain, R327 achieved bactericidal effect at concentrations 600, 1,200 ppm and 2,400 ppm (2X – 8X MIC), while **achieving a BLOQ at 2,400 ppm** (8X MIC) in 24 hour counts.
- R327 further demonstrated **bactericidal effect against *C. perfringens*** at 500 ppm, 1,000 ppm, 2,000 ppm and 4,000 ppm (1X – 8X MIC) respectively, **showing efficacy as early as 30 minutes**, and a **BLOQ at these concentrations** in 24 hour counts.

S. pyogenes is a species of Gram-positive bacteria and can cause life-threatening infections such as Scarlet Fever, Bacteremia (bacteria in the blood), Pneumonia, Necrotizing Fasciitis, Myonecrosis and Streptococcal Toxic Shock Syndrome. *C. perfringens* is also a Gram-positive pathogen that is a leading cause of myonecrosis and a species that thrives in nil/low oxygen environments, which can cause infections in diabetic wounds/ulcers – a common characteristic of bacterial anaerobes.

Chief Scientific Officer, Michele Diliza, said, "*While necrotizing fasciitis is a rare and extremely challenging disease for physicians to manage, it is highly traumatising for patients and their families, often leading to serious complications and even death. A broad spectrum anti-infective with rapid efficacy has the potential to significantly change the treatment paradigm and save lives. We have been thoroughly impressed with the efficacy that R327 has demonstrated thus far, as it reinforces our belief in the potential of this compound against such aggressive, life-threatening bacteria.*"

This announcement has been approved for release by Recce Pharmaceuticals Board

[1] Stevens, D. L., Aldape, M. J., & Bryant, A. E. (2012). Life-threatening clostridial infections. *Anaerobe*, 18(2), 254-259.
[2] https://www.ncbi.nlm.nih.gov/books/NBK430756/

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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE) is pioneering the development and commercialisation of New Classes 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 is unique and comprised of broad-spectrum synthetic polymer antibiotics RECCE® 327, RECCE® 435, and RECCE® 529 for viral infections with unique mechanisms of action against hyper-mutation on bacteria and viruses, respectively.

Patented lead candidate RECCE® 327 as an intravenous therapy, is being developed for treatment of serious and potentially life-threatening infections including sepsis due to Gram-positive and Gram-negative bacteria including their superbug forms. Recce's new antibiotic compound, RECCE® 435, has been formulated for oral use.

The FDA has awarded RECCE® 327 *Qualified Infectious Disease Product* designation under the *Generating Antibiotic Initiatives Now* (GAIN) Act – labelling it for Fast Track Designation, plus 10 years of market exclusivity post approval. Further to this designation, RECCE® 327 has been included on The Pew Charitable Trusts *Global New Antibiotics in Development Pipeline* as the only synthetic polymer and sepsis drug candidate in development.

Recce wholly owns its automated manufacturing, ready to support first-in-human clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of RECCE® technologies targeting synergistic, unmet medical needs.

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