ASX Announcement

Recce Pharmaceuticals
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Positive Patients Update – Special Access Scheme

Highlights:

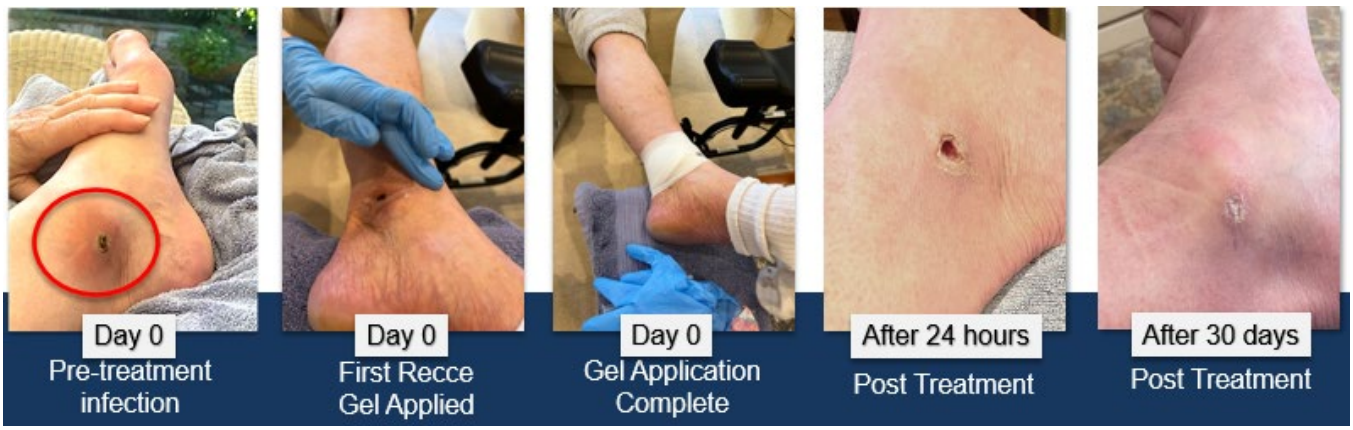
- **New RECCE® 327 Gel (R327G) indicates positive clinical response in the treatment of multiple antibiotic-resistant infections under TGA Special Access Scheme Category A (SAS – Category A)**
- **R327G administered via new Gel formulation – *ex vivo* burn wound study indicating 4 to 5-log reduction (>99.99%) against Methicillin-resistant *Staphylococcus aureus***
- **Clinical trial preparations underway across multiple unmet medical needs**

Sydney Australia, 8 August 2023: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**), the Company developing a New Class of Synthetic Anti-Infectives, is pleased to update upon Therapeutic Goods Administration (TGA) Special Access Scheme (SAS) Category A utilisation of RECCE® 327 Gel (R327G) by a qualified medical practitioner across patients suffering antibiotic-resistant Gram-positive and Gram-negative bacterial infections.

RECCE® 327 (R327) and R327G are experimental compounds, not market approved for use in humans; safety and efficacy are to be determined by present clinical studies. The results shown below must be considered anecdotal; however, are presented in the interest of continuous disclosure obligations and are not part of any present clinical trials.

Patient Case Study Example A

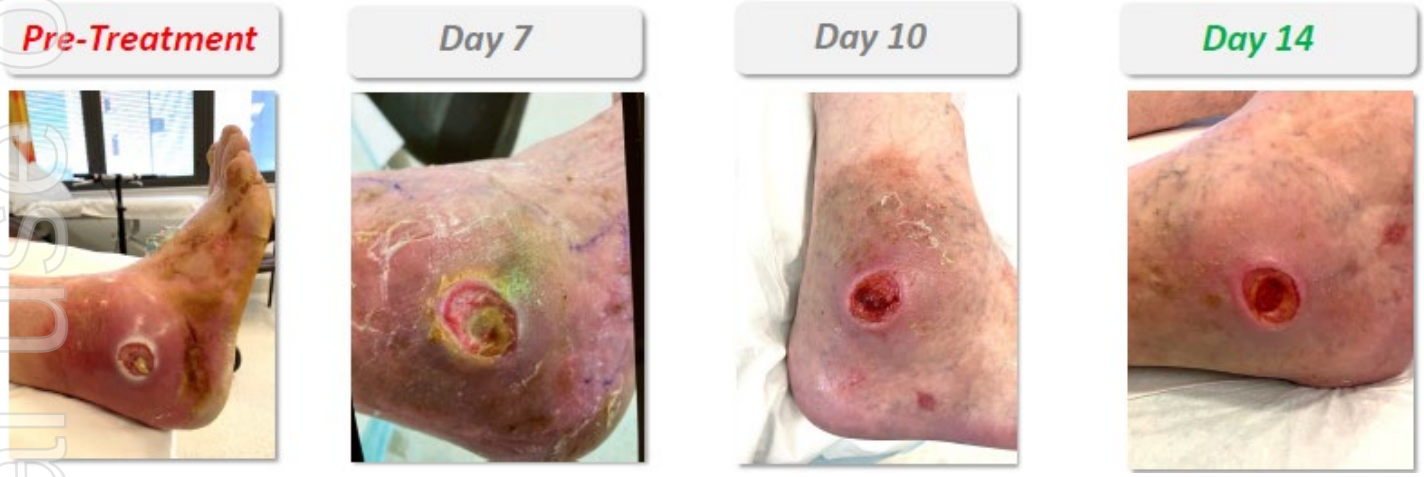
70–75-year-old male, puncture wound from metal spike injury. Unresponsive to all prior antibiotics, infection spreading and preparing for surgical intervention.



After 24 hours, with only one dosing application of R327G, the infection had clinically responded (no pre-treatment wound debridement was required). Furthermore, the redness and swelling of the wound was reduced with no reported stinging at any point. At 30 days post-treatment, the wound had successfully healed and closed.

Patient Case Study Example B

72-year-old male, with type 2 diabetes, unresponsive to all prior antibiotics. Peripheral Vascular disease and neuropathy.



Pre-treatment of R327G showed significant bacterial infection, redness and swelling. Upon applying R327G, after seven days, the initial redness and swelling had minimised, with the wound healing and drying up. Day 10 post R327G treatment showed no signs of infection, no signs of pus formation and the wound continuing to clear up and heal. Day 14 post R327G treatment, the wound has significantly improved and R327G was well tolerated. Surgical intervention (commonly limb amputation in diabetic patients) was averted.

Other patient case studies have been not disclosed for matters of confidentiality; however, include the successful treatment of (but not limited to): Necrotising fasciitis (flesh eating bacteria), Osteomyelitis (bone infection) and complex skin structure bacterial infections.

Patients have been treated pursuant to the SAS-Category A; a notification pathway that can be accessed by health practitioners on behalf of a prescribing medical practitioner for patients who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment, and does not constitute a clinical trial.[1]

[1] https://www.tga.gov.au/sites/default/files/special-access-scheme-guidance-for-health-practitioners-and-sponsors.pdf

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Background results supporting potential of R327 as a Gel formulation

An independent clinical research organisation conducted an animal study where multiple R327G formulations were tested for efficacy against Methicillin-resistant *Staphylococcus aureus* (MRSA) (listed "High" on the WHO Priority Pathogen list of antibiotic-resistant bacteria) using an *ex-vivo* porcine (pig) skin model. The formulation also included in the study is that being used in human clinical trials as an intravenous use (liquid).

After 24 hours, R327G had achieved a 4 to 5-log reduction (99.99% - 99.999% reduction) in all formulations and had the greatest overall efficacy against MRSA. MRSA infections are one of the leading causes of hospital-acquired infections and is commonly associated with significant morbidity, mortality, length of stay, and cost burden[2]. MRSA most often causes skin infections and if left untreated, can become severe and cause sepsis[3].

Treatment		Log_{10} Reduction from Control (Mean ± SD)
1hr	Control	N/A
	RECCE® 327 I.V.	3.04 ± 1.20
	RECCE® 327 Gel (1.0% CMC)	2.10 ± 1.23
	RECCE® 327 Gel (2.0% CMC)	0.90 ± 0.13
24hr	Control	N/A
	RECCE® 327 I.V.	4.97 ± 0.11
	RECCE® 327 Gel (1.0% CMC)	4.32 ± 0.81
	RECCE® 327 Gel (2.0% CMC)	5.07 ± 0.26

Numerical values for Methicillin-resistant Staphylococcus aureus Log_{10} Reduction

*Understanding logs (e.g. of a small colony of 1 million MRSA bacteria)**
A 1-log kill reduces the colony to 100,000 MRSA bacteria after a 90% reduction
A 2-log kill reduces the colony to 10,000 bacteria after a 99% reduction
A 3-log kill reduces the colony to 1,000 bacteria after a 99.9% reduction
A 4-log kill reduces the colony to 100 bacteria after a 99.99% reduction
A 5-log kill reduces the colony to 10 bacteria after a 99.999% reduction
A 6-log kill reduces the colony to 1 MRSA bacterium after a 99.9999% reduction

The Company engaged Linnaeus Bioscience (leading experts in bacterial Mechanism of Action analysis) based in San Diego, USA to test R327G antimicrobial activity at different formulations.

The image below shows a clearing in a lawn of *Escherichia coli* (ATCC 25922) on solid LB-agar media. Each of the gel formulations (R327G "a, b, c and d") produced a zone of clearing approximately 13mm in diameter – indicating each formulation is active and demonstrates

[2] https://www.ncbi.nlm.nih.gov/books/NBK482221/

[3] https://www.cdc.gov/mrsa/index.html#:~:text=Methicillin%2Dresistant%20Staphylococcus%20aureus%20(MRSA),-Related%20Pages&text=Staph%20bacteria%20are%20usually%20harmless,of%20resistance%20to%20some%20antibiotics.

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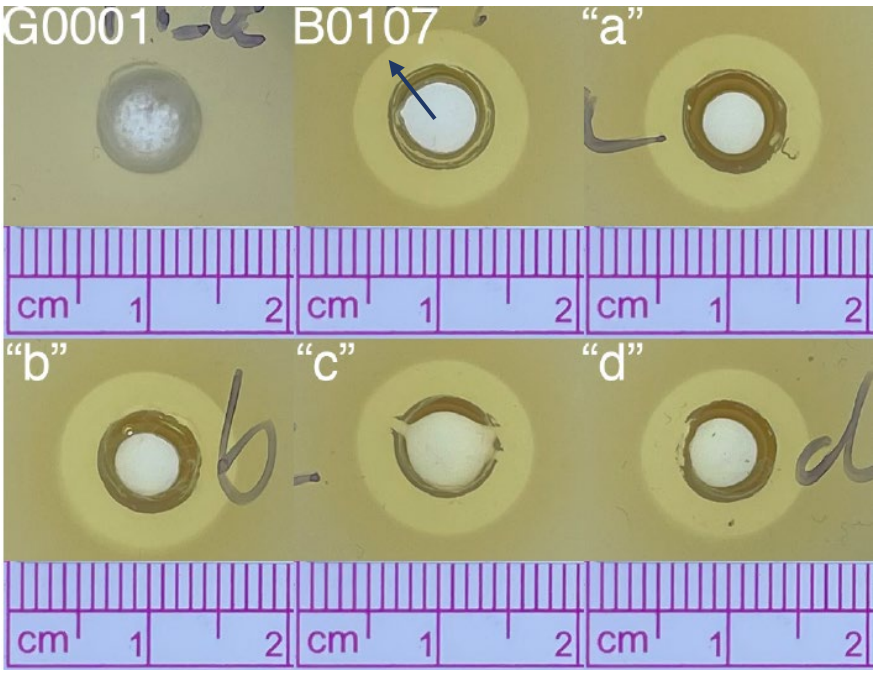
similar potency to R327 liquid (B0107) (formulation used in intravenous human clinical trials) on solid media.



Monitored dispersion is observed outside the dark ring (well) – G0001 (placebo control) had no effect upon the *E. coli*; however, R327 and R327G successfully dispersed outwards through bacterial lawn.

The above topical results form part of discussions with the Burn Wound team of Fiona Stanley hospital, with the view to progress RECCE® compounds to Stage 2 investigations including the potential use of R327G among patient populations.

Separately, Clinical Trial applications for the topical utilisation of R327G in common and complicated skin and soft tissue infections are progressing in line with these welcomed developments.

Chief Executive Officer of Recce Pharmaceuticals James Graham said, "Antibiotic Resistance is globally recognised as one of the greatest threats to human health today. To see Recce making a difference to patients in such great medical need before us, is another welcomed sign of new hope in the fight against drug-resistant superbugs. We look forward to building upon these successes among the present and future clinical trials ahead".

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 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 as an orally administered therapy for bacterial infections; and RECCE® 529 for viral infections. Through their multi-layered mechanisms of action, Recce's anti-infectives have the potential to overcome the hypercellular mutation of bacteria and viruses – the challenge of all existing antibiotics to date.

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 world's only synthetic polymer and sepsis drug candidate in development. RECCE® 327 is not yet market approved for use in humans with further clinical testing required to fully evaluate safety and efficacy.

Recce wholly owns its automated manufacturing, which is supporting present clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of its technologies targeting synergistic, unmet medical needs.

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