Recce Pharmaceuticals
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ACN 124 849 065

Additional Positive Patient Cases – Special Access Scheme

Highlights:

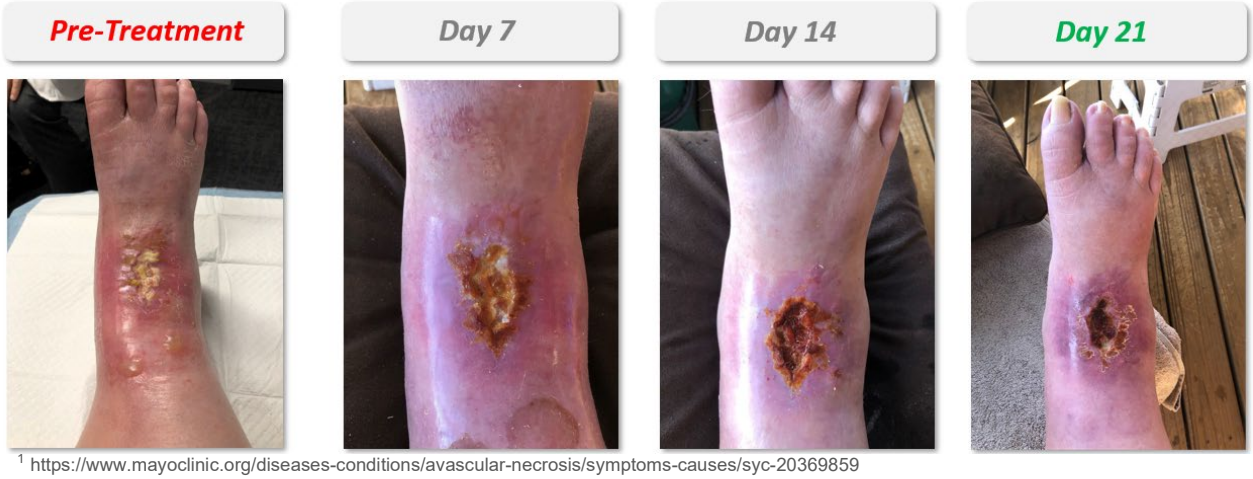
- **RECCE® 327 Gel (R327G) indicates positive clinical response in the treatment of multiple antibiotic-resistant infections under TGA Special Access Scheme Category A (SAS – Category A)**
- **Five total patients treated under TGA SAS Category with R327G – all responded well to treatment with complete eradication of antibiotic-resistant infections**
- **Clinical trial preparations underway for use of R327G as a topical application**

Sydney Australia, 31 August 2023: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**), (the **Company**), the Company developing a New Class of Synthetic Anti-Infectives, is pleased to report on further patient case studies, using RECCE® 327 Gel (R327G) under the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS) Category A by a qualified medical practitioner across patients suffering antibiotic-resistant Gram-positive and Gram-negative bacterial infections.

R327G is an experimental compound, 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 C

51-year-old female with a significant wound infection post ankle infusion surgery. Diagnosed with arthritis on her right ankle due to talar avascular necrosis (death of bone tissue due to a lack of blood supply[1]).



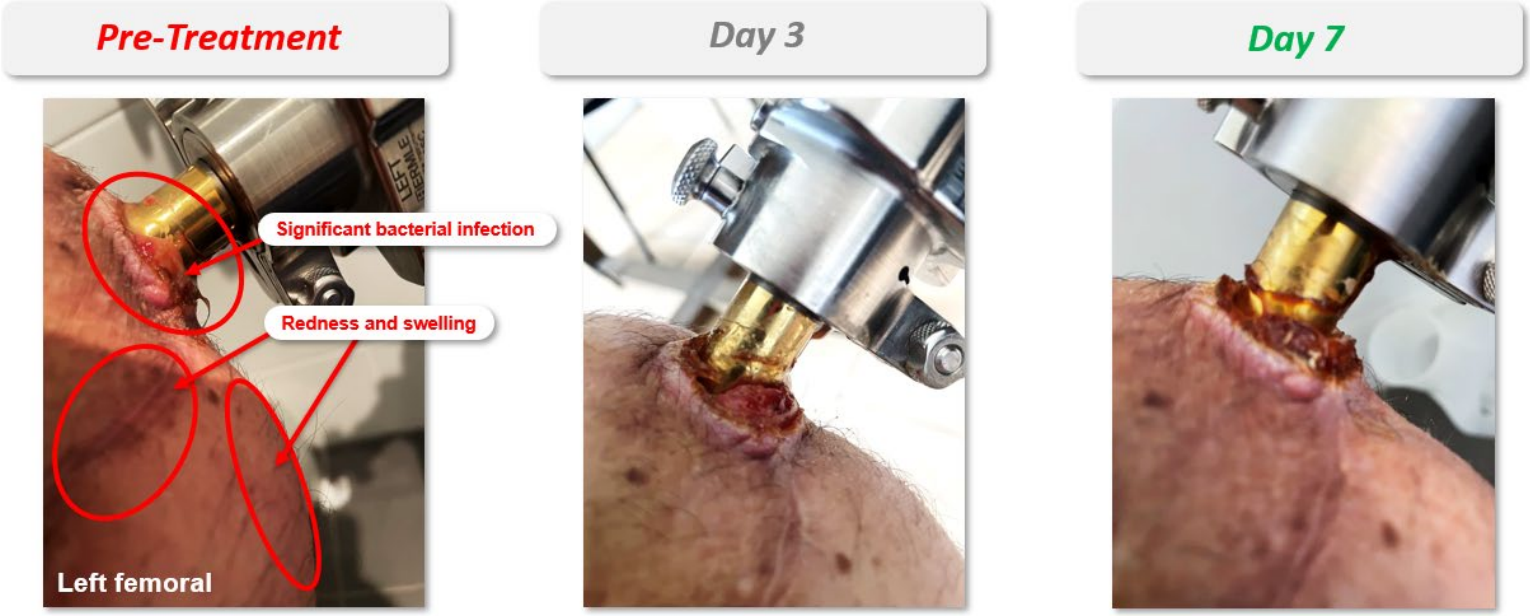
[1] https://www.mayoclinic.org/diseases-conditions/avascular-necrosis/symptoms-causes/syc-20369859

Pre-treatment wound swab on Day 0 showed a growing culture of both Gram-positive and Gram-negative bacilli – a deadly pathogen that produces spores, which can survive in environments for many years[2]. Patient A's slow healing wound was unresponsive for 5-6 weeks to two widely used antibiotics globally[3] for bacterial infections – Augmentin (Amoxicillin) and Keflex (Cefalexin).

Day 7 post R327G treatment, the initial redness and swelling of the wound had minimised and found to be drying up. Day 14 post R327G treatment, there were no signs of bacterial growth surrounding the wound; and at Day 21 post-treatment, the wound had successfully healed, closed and dried up with no signs of bacterial infection. R327G treatment was well tolerated when applied daily.

Patient Case Study Example D

51-year-old male, involved in a motor bike accident in 2017, was required to have an amputation above the knee. In 2018, the patient received an osseointegration (bone ingrowth metal implant). Recurrent infection on the left femoral (thigh). Not responding to oral and intravenous antibiotics.



Pre-treatment of R327G showed significant bacterial infection, redness and swelling around the implant (upper left thigh). Post three days after application of R327G, the initial redness and swelling had minimised, with the wound healing and drying up. Day 14 post-treatment showed wound was dried up and had improved with no signs of redness or swelling. R327G was applied daily and was well-tolerated.

[2] https://www.ncbi.nlm.nih.gov/books/NBK470553/
[3] https://www.ncbi.nlm.nih.gov/books/NBK538164/

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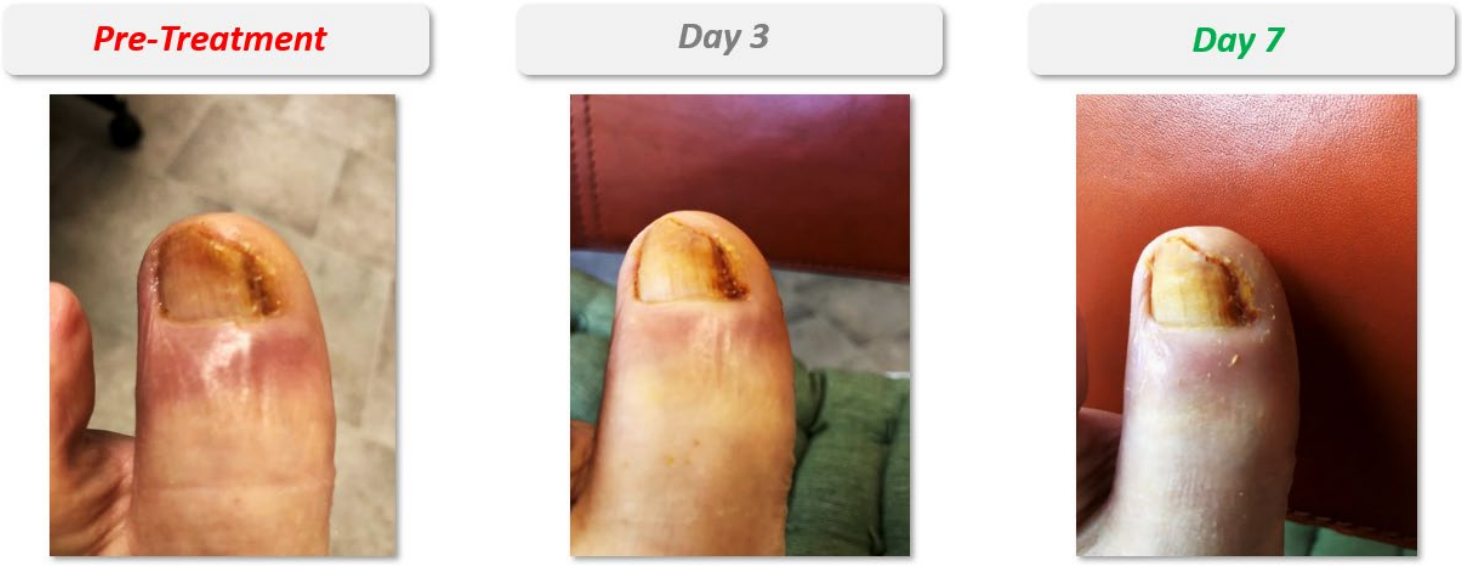
Patient Case Study Example E

84-year-old male with osteomyelitis (serious infection of the bone) on his left big great toe, not responding to antibiotics.



Pre-treatment (Day 1) X-rays showed infection deep within the underlying bone, tissue and around the nail, with signs of initial biofilm formation. After 3 days of R327G treatment, the wound is drying up with infection clearing and the toe responding well to treatment. Day 7 post R327G treatment showed wound completely dried up, no signs of biofilm surrounding toenail and swelling significantly reduced. Surgical intervention (commonly amputation in diabetic patients), which was the next step for this patient, was averted.

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.[4]

Chief Executive Officer of Recce Pharmaceuticals James Graham said, “We are thrilled to see R327G having a real-life impact with patients, especially those not responding to commonly used antibiotics thanks to the TGA’s special access scheme. 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.

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

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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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