ASX Announcement

Phase I/II Clinical Trial for the Treatment of Burn Wound Infections – Stage 1 Data Analysis Complete

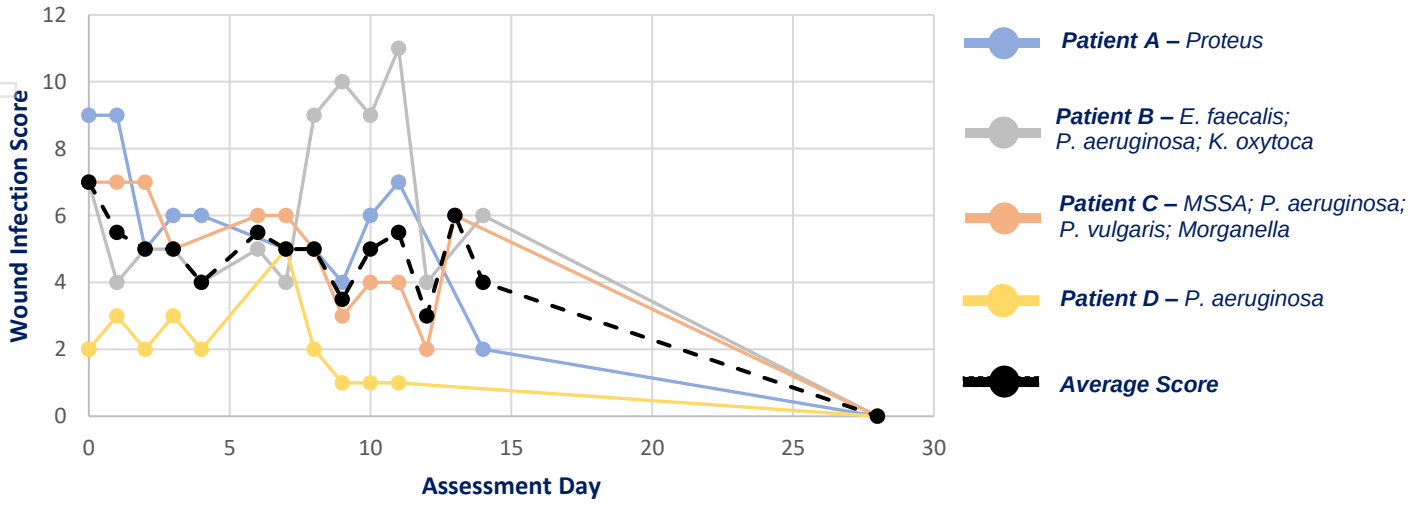
Highlights:

- **Bacterial infections successfully treated with RECCE® 327 in patients treated to date**
- **Deadly bacterial pathogens treated include those identified by World Health Organisation as major threats to human health**
- **Clinical trial progressing to a 'head-to-head' study against current standard of care – Stage 1 of investigator-led now moving to Stage 2, use of RECCE® 327 Gel**

SYDNEY Australia, 21 August 2023: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing a new class of Synthetic Anti-infectives, is pleased to announce Data Analysis complete for its Phase I/II topical clinical trial of RECCE® 327 (R327) for the treatment of burn wound infections.

Clinicians have reported visible reduction in bacterial infection within the first 24 hours of R327 treatment, with R327 demonstrating broad spectrum antibiotic activity against Gram-positive and Gram-negative pathogens (listed on the WHO Priority Pathogen list of antibiotic-resistant bacteria[1]), which are defined as multidrug-resistant and difficult to treat.

Patient Wound Scores with Associated Bacterial Cultures



[1] *https://www.who.int/news/item/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed*

Endpoints of the trial include clinical wound assessment (graded for specific parameters such as erythema, hyper granulation, swelling, discharge) and microbial cultures of wound swabs. Scoring the severity of a diabetic foot wound infection may help assess the severity, determine the type and urgency of antibiotic and surgical treatment needed, and predict clinical outcomes[2].

All patients treated with R327 showed good indications of safety and tolerability to the compound. Observations from the study indicate if a dose or two of R327 is missed over a period then the wound can deteriorate, a typical observation with interrupted wound treatments. Of those who did not complete dosing, one required systemic antibiotics for unrelated co-morbidities, which immediately disqualified them from continuing the study. The other, a young patient, post wound debridement surgery, with significant, painful burns, that did not respond well to gentle spray application of a cold (R327) solution to the newly raw wound surface. No serious adverse events have been reported among patients.

This West Australian Government sponsored study has led to multiple opportunities such as: the commencement of a Phase I/II Diabetic Foot Infection trial (largest in Australia), use of RECCE® 327G (R327G) as a topical agent on patients under the TGA Special Access Scheme – Category A, and interest from military organisations for the use of R327 and R327G.

Recruitment has now concluded for Stage 1 of the investigator-led clinical trial due to the Fiona Stanley Hospital Burns Unit experiencing difficulty recruiting appropriate patients said to be primarily due to implementation of COVID protocols resulting in preventative, systemic, antibiotic infection control practices. This led to patients not meeting protocol requirements (no prior antibiotic treatment prior to enrolment), thus limiting the recruitment of the study.

In the interest of accessing a greater patient population, clinical investigators are actively preparing a new protocol in line with progress objective of next stage 'Head-to-head' investigation. Stage 2 Clinical trial is expected to be a randomised 'head-to-head' in patients with infected burn wounds, where R327G treatment is compared to existing treatment standard of care.

James Graham, Chief Executive Officer of Recce Pharmaceuticals Ltd said, "We thank the West Australian Government for sponsoring this investigator led topical burn wound infection trial. The patient data received has paved the way to advance this new class of anti-infective as a topical application against deadly bacterial pathogens and a broad range of infectious diseases beyond. We look forward to launching Stage 2 as this study has facilitated."

This announcement has been approved for release by Recce Pharmaceuticals Board.

[2] *https://pubmed.ncbi.nlm.nih.gov/19671126/*

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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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