Recce Pharmaceuticals
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Update on Phase I/II Clinical Trial for the Treatment of Burn Wound Infections

Highlights:

- **Broad spectrum antibiotic activity on bacterial Burn Wound infections with visible infection reduction <24 hours on all patients to date**
- **All infections cleared within 5 days (acute) or 7 days (chronic); clinicians reducing treatment windows per protocol/positive patient indications**
- **Burn wound infections consisted of Gram-positive and Gram-negative bacteria, including multi-drug resistant and 'biofilm' categorised forms**
- **Update in-line with reaching clinical trial end-points; patient recruitment on-going**

SYDNEY Australia, 7 December 2021: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing New Classes of Synthetic Anti-infectives, is pleased to provide an update on its Phase I/II clinical trial for the treatment of burn wound infections.

The West Australian Health department sponsored clinical trial at Fiona Stanley Hospital is assessing the safety and efficacy of RECCE® 327 (R327) in patients with infected burn wounds under Trial ID ACTRN12621000412831.

Dr Ed Raby, Study Investigator, said: "We are highly encouraged by the initial success of R327 in this topical Phase I/II trial. Patients with burn wounds often suffer severe bacterial infections that are painful, prevent wound healing and can even result in death if not properly treated. Because many of these bacteria are resistant to most available drugs, we are pleased by the potential in R327 offering a treatment option for patients in need."

Characterisation of swabs from participant burn wounds prior to treatment with R327 identified a wide range of pathogenic bacteria including **Gram-positive** (*Staphylococcus aureus*[1] and *Staphylococcus lugdunensis*) and **Gram-negative** (*Pseudomonas*

[1] https://pubmed.ncbi.nlm.nih.gov/18534827/

aeruginosa[2]*, Klebsiella pneumoniae*[3]*, Morganella morganii, Proteus vulgaris, Proteus mirabilis*) bacteria, some of which are defined as multi-drug resistant and categorised as difficult to treat due to biofilms.

Clinicians have reported visible reductions in bacterial infection within the first 24 hours of R327 treatment among patients treated to date. Patients with acute infected wounds have indicated a complete clinical response, requiring no further treatment. As a result, clinicians have adopted a significantly shorter five (5) day treatment protocol. Patients with chronic or significant surface area wounds see a similar outcome by day seven (7). Treatment protocols for both groups of patients were initially proposed to comprise a 14-day period.

As is common in therapeutic activity on sensitive wound surfaces, patients noted a minor, brief stinging sensation as the solution reached the area of infection, which appeared to subside in line with reduction in bacterial loads. No adverse effects or abnormalities have been reported among patients.

The study is on-going, with target patient enrolment/treatment expected early 2022, allowing full data-set reporting to follow.

James Graham, Chief Executive Officer of Recce Pharmaceuticals added: “We are pleased with the progress of our lead compound, R327 in patients harbouring serious burn wound infections. This initial update builds upon strong pre-clinical data demonstrating fast and efficient killing activity against common and problematic bacterial strains, and we are excited for the potential of R327 in the clinic. We look forward to updating shareholders of further human clinical data points as this trial progresses.”

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

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7105944/
[3] https://bmcproc.biomedcentral.com/articles/10.1186/s12919-019-0176-7

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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE, FSE: R9Q) 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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