

ASX Announcement

Multiple Patients Dosed in Topical Phase I/II Clinical Trial

Highlights:

- **Multiple Patients Dosed in Phase I/II clinical trial, an important human clinical milestone**
- **No adverse symptoms reported - R327 well stocked in hospital pharmacy for further patient utilisation**
- **Interim data readouts expected this quarter with full data end CY Q4 2021**

Sydney Australia, 12 July 2021: Recce Pharmaceuticals Ltd (**ASX:RCE**) (**FSE:R9Q**), the Company developing New Classes of Synthetic Anti-infectives is pleased to announce multiple patients have been dosed with RECCE[®] 327 (R327) in a topical Phase I/II clinical trial at the Fiona Stanley Hospital Burns Unit in Perth, Western Australia.

The single-centre, 30 patient, prospective, interventional study, aims to assess the clinical effectiveness and safety of R327 as a spray-on antibiotic in the treatment of infected burn wounds in adults (Trial ID: ACTRN12621000412831).

Clinical Investigator Dr Edward Raby said, “There is a major unmet medical need among patients with severe burn wound infections with this important study a key part in our work to find a solution. The spray-on administration makes application easy, with the potential patient benefit having real world impact beyond.”

Burn wound infections continue to cause significant health problems for patients following a range of burn injuries with current therapeutic options that are sub-optimal and often associated with delayed wound healing. Methicillin-resistant *Staphylococcus aureas* (MRSA) is one of the leading organisms causing invasive infection in burns across the world, with burn units reporting rates of infection greater than 50%.

Sponsored by the WA Health Department and conducted at Fiona Stanley Hospital, the clinical trial is undergoing two dosing schedules with ten participants receiving R327 daily and a further twenty receiving R327 three times a week as a spray-on administration, over a 14 day study period.



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Recce Pharmaceuticals Chief Executive Officer James Graham said, “We are honoured to be working with such a dedicated team of world-leading experts at Fiona Stanley Hospital and look forward to supporting them and their patients in tackling the range of difficult to treat infections faced on a daily basis.”

More information on this trial can be found at the Australia New Zealand Clinical Trials Registry under the trial ID ACTRN12621000412831 – *Proof of concept study of RECCE 327 topical antibiotic therapy for infected burn wounds in adults.*

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 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 has been developed for the treatment of blood infections and sepsis derived from *E. coli* and *S. aureus* 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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