

## **ASX Announcement**

## Positive Safety Data from Fifth Cohort of Phase I Clinical Trial of RECCE® 327 and Initiates Sixth Cohort at 4,000mg

## Highlights:

- In Cohort 5, RECCE<sup>®</sup> 327 (R327) demonstrated good safety and tolerability in subjects intravenously dosed at 2,000mg
- Independent Safety Committee approves Cohort 6 dosing at 4,000mg; an 80-fold increase from Cohort 1 at 50mg
- Subjects in Cohort 6 have been recruited and dosing is underway

**SYDNEY Australia, 20 May 2022:** Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing a New Class of Synthetic Anti-infectives, today announced that in Cohort 5 of a Phase I clinical trial, R327 demonstrated a good safety and tolerability profile among 10 healthy male subjects intravenously dosed at 2,000mg. An Independent Safety Committee has unanimously approved Cohort 6 to commence at 4,000mg, with subjects recruited and dosing underway.

James Graham, Chief Executive Officer of Recce Pharmaceuticals Ltd said, "This data builds on previous cohorts and validates RECCE® 327's compelling safety and tolerability profile, with the potential to serve as a solution for patients with sepsis. We are greatly encouraged by this progress and moved quickly to commence dosing of Cohort 6, evaluating R327 in high doses of 4,000mg."

The Phase I trial is an ascending dose, randomised, placebo-controlled, parallel, double-blind, single-dose study being conducted at Adelaide's CMAX clinical trial facility. The study is evaluating the safety and pharmacokinetics of R327 in 7-10 healthy subjects per dose, across eight sequential dosing cohorts of 50-16,000mg (Trial ID ACTRN12621001313820). The study is on track to have all Phase I dosing complete by Q2 2022.

According to PEW Charitable Trusts global antibiotic pipeline review, R327 is the only clinical-stage new class of antibiotic in the world being developed for sepsis, the largest unmet medical need in human health<sup>1</sup>.

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

 $<sup>^{1}\</sup> https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2017/nontraditional-products-for-bacterial-infections-in-clinical-development$ 



## **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 antiinfective pipeline seeks to exploit the unique capabilities of its technologies targeting synergistic, unmet medical needs.

