ASX Announcement



Positive Safety Data from Sixth Cohort of Phase I Clinical Trial Evaluating Healthy Subjects Intravenously Dosed with RECCE® 327

Highlights:

- 10 subjects in Cohort 6 intravenously dosed; RECCE® 327 at 4,000mg demonstrated good safety and tolerability
- Independent Safety Committee to review Cohort 6 data anticipate recommendation to proceed
- Cohort 6 dosing at 4,000mg completed 80-fold increase from Cohort 1 at 50mg

SYDNEY Australia, 21 June 2022: Recce Pharmaceuticals Ltd (**ASX:RCE, FSE:R9Q**) (the **Company**), the Company developing a New Class of Synthetic Anti-infectives, is pleased to report Phase I intravenous (IV) clinical trial of RECCE® 327 (R327) Cohort 6 Six at 4,000mg (80-fold increase on Cohort One 50mg dose) indicating a good safety and tolerability profile among 10 healthy male subjects. A review of the data will be conducted by an Independent Safety Committee with an expected recommendation to commence recruiting for Cohort Seven.

James Graham, Chief Executive Officer of Recce Pharmaceuticals Ltd said, "We are pleased with these data which builds on previous results and strongly supports the potential of RECCE® 327 as a new treatment option for patients with sepsis. We look forward to continuing to work with the Independent Safety Committee and further evaluating RECCE® 327's safety and tolerability profile in additional cohorts."

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 (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 health¹.

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

¹ https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2017/nontraditional-products-for-bacterial-infections-in-clinical-development



Chief Executive Officer Media and Investor Relations (AU)

Media and Investor Relations (USA)

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.



Media and Investor Relations (USA)