ASX Announcement

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

Highlights:

- **10 subjects in Cohort 7 intravenously dosed; RECCE® 327 at 6,000mg**
- **Independent Safety Committee Cohort 7 data review underway** – anticipate recommendation to proceed to a Cohort 8
- **Study objectives broadly achieved** – now 'dose-ceiling' focused with dose escalation increments considered welcomed bonus data
- **R327 dosing broadly in efficacy range** based on animal models – Phase II (efficacy) to determine
- **Next Phase preparations well underway** – not waiting on bonus data-sets

SYDNEY Australia, 22 August 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 7 at 6,000mg (120-fold increase on Cohort One 50mg dose) over 1 hour I.V. infusion, with no serious adverse effects among 10 healthy male subjects.

An Independent Safety Committee is reviewing the latest patient dosing data and is expected to recommend go ahead with Cohort 8 dosing of R327. The Company notes 6,000mg as being broadly efficacious in animal models previously; with following phases (efficacy) necessary to fully determine with preparations well underway.

James Graham, Chief Executive Officer of Recce Pharmaceuticals Ltd said, "We are thrilled to have completed dosing of 6,000mg (6 grams) via 1 hour I.V. infusion in our Phase I clinical trial. Achieving a 120-fold increase from Cohort 1 (50mg) with anticipation to soon begin a cohort 8 continues to build the safety and tolerability profile as a potential new-class of anti-infectives"

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).

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[1].

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

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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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