ASX Announcement

Recce Pharmaceuticals
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Safety Committee Clears Next Dose - Phase I Clinical Study of RECCE® 327 (1,000mg I.V)

Highlights:

- **Independent Safety Committee unanimously recommends Cohort 4 (R327 – 1,000mg I.V.) to go ahead; a 20-fold increase on Cohort 1 dose (50mg)**
- **Cohort 4 subjects recruited - R327 1,000mg I.V. dosing starts today**
- **All subjects to be dosed this week**

SYDNEY Australia, 7 March 2022: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing a New Class of Synthetic Anti-infectives, is pleased to report an Independent Safety Committee data review of 10 healthy human subjects intravenously dosed in the Phase I intravenous (IV) clinical trial of RECCE® 327 (R327), demonstrating good safety and tolerability – unanimously recommending Cohort 4 (R327, 1,000mg I.V.) to go ahead.

James Graham, Chief Executive Officer of Recce Pharmaceuticals Ltd said, "Recommendation to start I.V. dosing of Cohort 4 (R327 I.V.; 1,000mg) is a wonderful endorsement for the compelling Safety and Tolerability profile demonstrated among 10 subjects of Cohort 3. With subjects in Cohort 4 recruited and dosing starting today, we are on-track to complete Cohort 4 this week."

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[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

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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