

ASX Announcement

Clarification - Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial of RECCE® 327

SYDNEY Australia, 1 July 2024: Recce Pharmaceuticals Ltd (**ASX: RCE, FSE: R9Q**) (the **Company**), the Company developing a new class of Synthetic Anti-infectives, wishes to clarify the announcement released on 28 June 2024 surrounding the completed Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial.

The Phase I/II clinical trial was an Open Label, Adaptive Design Evaluation, Crossover Study of the Safety, Pharmacokinetics and Pharmacodynamics of Various RECCE® 327 (R327) Intravenous Dose and Infusion Rates.

The primary trial outcomes were to evaluate the safety and tolerability of R327 administered at various infusion rates ranging from 15 to 45 minutes in healthy male and female participants, and to assess the plasma pharmacokinetics of R327 using the same infusion rates. The secondary trial outcomes focused on evaluating the concentration of R327 in urine at various doses and infusion rates, as well as examining the *ex vivo* pharmacodynamics, specifically the minimum inhibitory concentration (MIC), of urine and blood samples from participants. Trial outcomes were successfully achieved

Participants in the trial received R327 via intravenous administration across a range of infusion times, with the duration of infusion and dose varying across the cohorts. The trial included a total of 25 participants, as stated in the announcement released on June 28, 2024. These participants were divided into five cohorts, each receiving R327 at different infusion times and doses. A control group was not used. The subject demographics consisted of healthy males and females aged 18-65.

- Cohort 1 (2,500mg, 45-min infusion rate) – nine trial subjects
- Cohort 2 (3,000mg, 30-min infusion rate) – four trial subjects
- Cohort 3 (3,000mg, 15-min infusion rate) – two trial subjects
- Cohort 4 (3,000mg, 20-min infusion rate) – four trial subjects
- Cohort 5 (4,000mg, 20-min infusion rate) – six trial subjects

An independent data review has been conducted and made the positive safety and efficacy conclusions stated in the announcement released 28th June 2024. A comprehensive data review will be conducted with results to be made available to the Company and expected to be in line with findings to date.

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



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