ASX Announcement



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

Highlights:

- 7 subjects in Cohort Two intravenously dosed; R327 subjects receiving 150mg
 meeting study end-points indicating to be safe and well tolerated at this dose
- Independent Safety Committee clears third study cohort to be dosed at 500mg a tenfold increase on Cohort one (50mg) and a threefold increase on Cohort two (150mg) per approved protocol
- Third Cohort dosing of R327 (500mg) on track to begin this this week

SYDNEY Australia, 18 January 2022: Recce Pharmaceuticals Ltd (ASX:RCE, FSE:R9Q) (the Company), the Company developing New Classes of Synthetic Anti-infectives, is pleased to report further positive data from its Phase I intravenous (IV) clinical trial of RECCE® 327 (R327), demonstrating safety and tolerability, among 7 healthy male subjects in Cohort Two. Based upon these clinical data readouts, an independent safety committee has approved a tenfold increase on the initial dosing of Cohort one (50mg) or threefold increase (from 150mg to 500mg) among 7-10 healthy subjects (Cohort Three). Subjects are expected to be recruited this week and dosed immediately thereafter at Adelaide's CMAX clinical trial facility.

James Graham, Chief Executive Officer of Recce Pharmaceuticals Ltd said, "We are pleased to see R327 (150mg) successfully tolerated as an intravenous infusion in Cohort Two subjects. Having successfully cleared two dosing levels (50mg and 150mg) we look forward to embarking upon this next significant milestone."

Cohort Two (R327 - 150mg) Complete – Demonstrated Safety and Tolerability

R327 was shown to be safe and well tolerated at the 150mg dose with no clinically significant changes in vital signs, clinical, adverse events, or laboratory parameters associated with R327.



The Phase I trial is an ascending dose, randomized, placebo-controlled, parallel, doubleblind, 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 health¹.

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

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 New Classes 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 (AU)