ASX Announcement

Recce Pharmaceuticals
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ACN 124 849 065

Safety Committee Approves High Dose of 4,000mg in Phase I/II Urinary Tract Infection/Urosepsis Rapid Infusion Clinical Trial

Highlights:

- **Independent Safety Committee unanimously clears RECCE® 327 (R327) increase to 4,000mg intravenously (I.V.) over 30 minutes**
- **R327 (3,000mg) successfully tested at four infusion times (15-mins, 20-mins, 30-mins, 45-mins and 1-hour) – increase to 4,000mg at identified potential optimum fast infusion time of 30 minutes**
- **6 participants (male/female) total - dosing to start/complete in near weeks**
- **Minimum Inhibitory Concentration (MIC) activity identified against among existing clinical samples, a dose optimisation exercise for regulatory purposes**

Sydney Australia, 26 April 2024: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**), (the **Company**), the Company developing a New Class of Synthetic Anti-Infectives, is pleased to report an Independent Safety Committee has approved an increase of R327 to 4,000mg (I.V.) over a fast infusion of 30 minutes. Subject recruitment underway and expected to start/complete dosing of 6 subjects in near weeks.

The Company has now dosed 3,000mg at multiple infusion times; 15-mins, 20-mins, 30-mins, 45-mins, and 1-hour. Dosing has successfully achieved Minimum Inhibitory Concentration (MIC) activity among existing clinical samples. The Company has identified 30 minutes as the potential optimum infusion time and increased to a higher concentration as per regulatory expectations to investigate R327's high concentration potential.

The efficacious potential of R327 via I.V. administration will be made available at the completion of this human clinical trial in line with study protocol. In a parallel clinical program, R327 applied topically against Diabetic Foot Ulcer Infections recently demonstrated its efficacious potential against a broad range of antibiotic-resistant infections.

Chief Executive Officer James Graham said "We're thrilled the independent safety committee has unanimously clearly an increased R327 dose to 4,000mg, over a 30 minute fast I.V. infusion. The high concentration potential to administer a broad spectrum anti-infective underscores the potential of a novel treatment for millions of patients worldwide that suffer from Urinary Tract Infection/Urosepsis each year."

More information on this trial can be found at the Australia New Zealand Clinical Trial Registry under the trial ID ACTRN12623000448640.

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

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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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