ASX Announcement

Recce Pharmaceuticals
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ACN 124 849 065

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

Highlights:

- **10 subjects in Cohort Four intravenously dosed; RECCE® 327 at 1,000mg indicating to be safe and well tolerated**
- **Independent Safety Committee to review Cohort Four data – expect recommendation to proceed – Cohort Five recruitment underway**

SYDNEY Australia, 30 March 2022: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing New Classes of Synthetic Anti-infectives, is pleased to report Phase I intravenous (IV) clinical trial of RECCE® 327 (R327) Cohort Four at 1,000mg (twenty-fold increase on cohort one 50mg dose), indicating a good safety and tolerability profile among 10 healthy male subjects.

James Graham, Chief Executive Officer of Recce Pharmaceuticals Ltd said, "Achieving a dosing level of 1,000mg is another significant milestone for the Company. Indicating R327 to be safe and well tolerated at a twenty-fold increase of the initial dosing level of 50mg is pleasing, not only for the unmet medical need of sepsis, but so too for synergies across our wider-infectious disease portfolio."

Cohort Four (R327 – 1,000mg) – Demonstrated Safety and Tolerability

R327 was indicated to be safe and well tolerated at 1,000mg with no clinically significant changes in vital signs or adverse events associated with R327.

The Phase I trial is an ascending dose, randomized, 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

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
+61 (02) 9256 2571
james.graham@recce.com.au

Media and Investor Relations (AU)
Andrew Geddes
CityPR
+61 (02) 9267 4511
ageddes@citypublicrelations.com.au

Media and Investor Relations (USA)
Jordyn Temperato
LifeSci Communications
jtemperato@lifescicomms.com

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 anti-infective pipeline seeks to exploit the unique capabilities of its technologies targeting synergistic, unmet medical needs.

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
+61 (02) 9256 2571
james.graham@recce.com.au

Media and Investor Relations (AU)
Andrew Geddes
CityPR
+61 (02) 9267 4511
ageddes@citypublicrelations.com.au

Media and Investor Relations (USA)
Jordyn Temperato
LifeSci Communications
jtemperato@lifescicomms.com