ASX Announcement

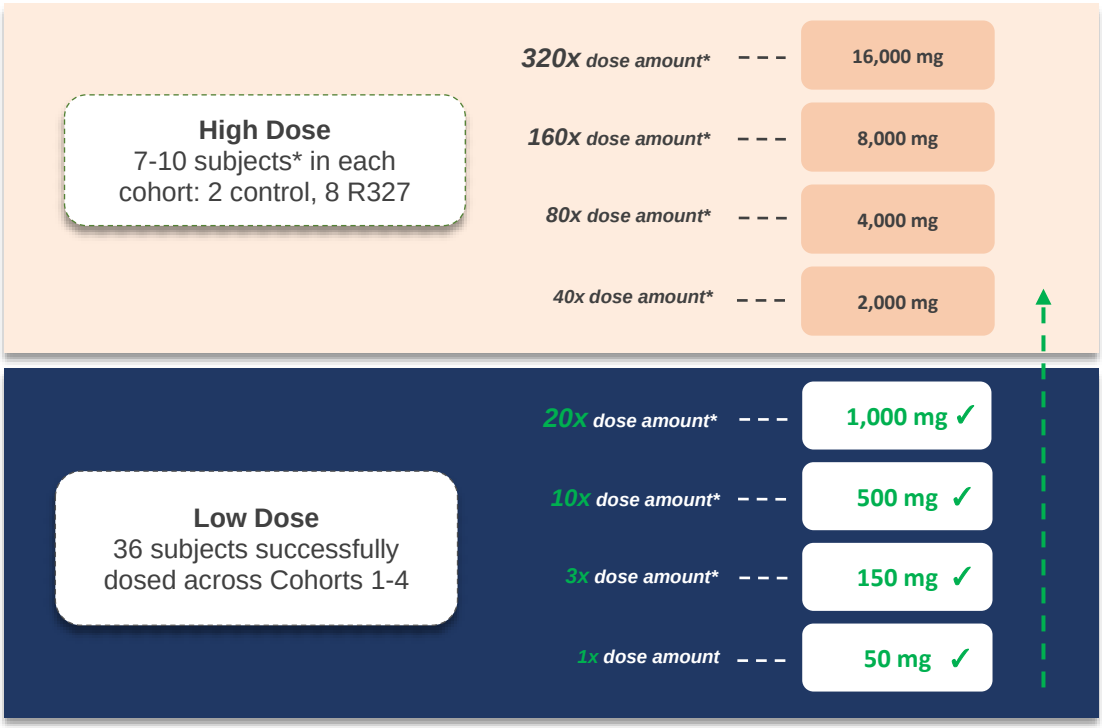
Recce Pharmaceuticals
recce.com.au
ACN 124 849 065

Phase I Clinical Trial of RECCE® 327 Advances to High Dose Level (2,000mg I.V)

Highlights:

- **36 human subjects successfully dosed in the Phase I intravenous (IV) clinical trial of RECCE® 327 (R327) – good safety & tolerability**
- **Independent Safety Committee affirms 'low-dose' cohort clinical trial complete, end-points achieved - recommends 'high dose' cohort dosing to begin**
- **Committee clears Cohort 5 (R327 – 2,000mg IV) dosing start - subjects recruited and dosing underway**

SYDNEY Australia, 12 April 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 dosed in the Phase I intravenous (IV) clinical trial of RECCE® 327 (R327), demonstrating good safety and tolerability at 1,000mg. 'Low-dose' cohorts data review complete, end-points achieved with unanimously recommendation to start 'high-dose' Cohort 5 (R327, 2,000mg IV).



**Dose increase fold based off 50mg*

James Graham, Chief Executive Officer of Recce Pharmaceuticals Ltd said, “Completing 1,000mg (R327 I.V) dosing, maintaining a good safety & tolerability profile among 36 human subject all cohorts - ideal completion of ‘low-dose’ cohorts seeing achieving clinical end-points. Recommendation to commence ‘high dosing’ at 2,000mg – a 40-fold increase from initial dosing of 50mg in Cohort 1 by the independent safety committee is a welcome validation with first human subject dosing now underway”.

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

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 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.

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