ASX Announcement

Recce Pharmaceuticals
recce.com.au
ACN 124 849 065

Patients to be Dosed in Phase I Intravenous Clinical Trial of RECCE® 327

Highlights:

- **10 healthy subjects recruited for Phase I human clinical trial**
- **Dosing in subjects will commence 16th December 2021**
- **R327 is the only clinical-stage antibiotic in development for sepsis in the world**
- **First cohort data on track for end of 2021 read-out**

SYDNEY Australia, 15 December 2021: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing New Classes of Synthetic Anti-infectives, has recruited 10 healthy male subjects (first cohort) in its Phase I intravenous (IV) clinical trial of its lead compound, RECCE® 327 (R327).

The Phase I trial is an ascending dose, randomized, placebo-controlled, parallel, double-blind, single-dose study, evaluating the safety and pharmacokinetics of R327 in healthy male subjects (Trial ID ACTRN12621001313820). The trial is being conducted at Adelaide's CMAX clinical trial facility and will enrol 80 healthy male subjects in total. R327 is administered as a single dose via a 1-hour IV infusion at a uniform rate, with all 80 subjects anticipated to have been dosed by the end of H1 2022.

James Graham, Chief Executive Officer of Recce Pharmaceuticals said: “We are very pleased to have the first cohort recruited for the clinical trial of R327 (IV). According to the Pew Charitable Trusts, R327 is the only clinical-stage antibiotic in the world being developed for sepsis, representing the largest unmet medical need in human health, the potential medical benefits are very significant indeed[1].”

The first cohort will be dosed over two days starting 16th December 2021, with the first set of interim safety subject data expected at the end of 2021. Further interim datasets on additional cohorts are expected to follow during H1 2022 as more cohorts of subjects are dosed.

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

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 antibiotics; RECCE® 327 as an intravenous and topical therapy; RECCE® 435 for oral administration; and RECCE® 529 for viral infections. Recce anti-infectives comprise of the world's first multi-layered mechanism of action able to overcome the hypercellular mutation of bacteria and viruses – the challenge of all existing antibiotics to date.

RECCE® 327 is being developed for the treatment of serious and potentially life-threatening infections including Sepsis due to Gram-positive and Gram-negative bacteria including their superbug forms. RECCE® 327 is not yet market approved for use in humans with further clinical testing required to fully evaluate safety and efficacy.

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 wholly owns its automated manufacturing supporting present human clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of its technologies targeting synergistic, unmet medical needs in human health.

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