ASX Announcement

Recce Pharmaceuticals Announces Expansion and Acceleration of Clinical Programs

Highlights:

- **Phase I (I.V) Safety/Tolerability study to Phase Ib/IIa multi-dose and sepsis efficacy study**
- **New Phase II clinical trial of R327 for treatment of Urinary Tract Infections (UTI)**
- **New Phase II study on Diabetic Foot Ulcer infections at leading NSW teaching hospital**
- **Multiple pre-clinical programs progressing to advanced stages**

SYDNEY Australia, 27 September 2022: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing New Classes of Synthetic Anti-infectives, is pleased to provide an updated timeline on its clinical programs with several significant data read-outs in 2022 and 2023.

Phase I (I.V) Safety/Tolerability study to Phase Ib/IIa multi-dose/sepsis efficacy study

Successful Phase Ia 1-hour single dose I.V. study has demonstrated R327 to be safe and well tolerated when administered over 60 healthy male adult volunteers, paving the way for a Phase Ib/IIa multi-dose and early-stage sepsis efficacy study with expected first subject dosing later this year and will run for approximately 12 months.

New Phase II clinical trial of R327 for treatment of Urinary Tract Infections (UTI)

Clinical data from the on-going Phase I (I.V.) clinical trial has revealed high concentrations of R327 residing in urine in the bladder of healthy volunteers. This insight is consistent with pre-clinical *in*-vivo kidney and UTI bacterial infection studies and supports primary excretion through the urine, suggesting opportunities for therapeutic activity in the human urinary tract.

UTIs are the most common outpatient infections in the US with a prevalence of 20% in women over the age of 65 and approximately 11% in the overall population with many being recurrent/antibiotic resistant infections. Moreover, approximately 25% of sepsis cases originate from the urogenital tract and specifically urosepsis represents a form of sepsis caused by a broad arrange of bacterial infections of the urinary tract, including cystitis, lower urinary tract and bladder infections and upper urinary tract and kidney infections.

While the Company works to finalise the study protocol, the Phase II clinical trial is expected to see first patient dosing in the early part of next year.

New Phase II study on Diabetic Foot Ulcer infections at leading NSW teaching hospital

Building upon success of the on-going topical burn wound infection program, the Company has built out its topical broad-spectrum bacterial infection treatment programs, through the design of a new Phase II clinical study for Diabetic Foot Ulcer infections at a leading Australian teaching hospital.

The clinical trial will assess R327 as a spray-on (topical) broad-spectrum antibiotic therapy for mild skin and soft tissue diabetic foot ulcers (DFU) with first patient dosing expected Q4 2022.

DFU is a chronic and devastating condition affecting an estimated 13% of North Americans[1]. DFU is an extremely severe condition with a probability of amputation within one year after the first ulcer or gangrene of 34.1% and a mortality rate of 5.5%[2].

Multiple Pre-clinical Programs Progressed to Advanced Stages

The Company's pre-clinical programs, focused on the treatment of significant unmet medical needs of infectious disease landscape, have demonstrated strong *in-vitro* and *in-vivo* activity of R327, including against a variety of deadly pathogens such as *Streptococcus pneumoniae*, *Helicobacter pylori,* and *Mycobacterium abscessus* (*M.*

[1] Zhang P. et al. – "*Global epidemiology of diabetic foot ulceration: A systematic review and meta-analysis*" (dagger) - Ann. Med. 2017;49:106–116.
[2] Won S.H. et al. – "*Risk factors associated with amputation-free survival in patient with diabetic foot ulcers.*" Yonsei Med. J. 2014;55:1373–1378.

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

abscessus) – a dangerous pathogen among cystic fibrosis patients.

Announcement and related presentation of independent studies across the Company's portfolio of pre-clinical programs is expected to be announced in the near term.

Recce Pharmaceuticals Chief Executive Officer James Graham said, "The significant progress Recce has made in the last 12 months continues to strengthen and build out the Company's anti-infective platform, paving the way to new and considerable infectious disease programs across a range of unmet medical needs. With good safety and encouraging signs of efficacy, we look ahead to new indications that can best adapt to physician and patient needs. We have therefore established an ambitious development plan, aiming to get new anti-infective therapies into market as expediently possible."

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

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 pioneering the development and commercialisation of 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 is unique and comprised of broad-spectrum synthetic polymer antibiotics RECCE® 327, RECCE® 435, and RECCE® 529 for viral infections with unique mechanisms of action against hyper-mutation on bacteria and viruses, respectively.

Patented lead candidate RECCE® 327 as an intravenous therapy, is being developed for treatment of serious and potentially life-threatening infections including sepsis due to Gram-positive and Gram-negative bacteria including their superbug forms. Recce's new antibiotic compound, RECCE® 435, has been formulated for oral use.

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 only synthetic polymer and sepsis drug candidate in development.

Recce wholly owns its automated manufacturing, ready to support first-in-human clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of RECCE® 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