ASX Announcement

Recce Pharmaceuticals
recce.com.au
ACN 124 849 065

First Cohort Dosed in RECCE® 327 Rapid Infusion Phase I/II UTI Clinical Trial

Highlights:

- **First cohort in Phase I/II UTI rapid infusion I.V. study successfully dosed 2,500mg of RECCE® 327 (R327) – will result in high peak urine concentrations (as already demonstrated in Phase I clinical trial)**
- **These high R327 concentrations in urine are expected to demonstrate a rapid kill rate of bacteria (in line with all pre-clinical UTI study results)**
- **First female dosed R327 I.V. 2,500mg (30-minute I.V. infusion) safely - as also observed in male participants**
- **Broadened patient population accelerating recruitment in Adelaide (CMAX) and Sydney (Scientia Clinical Research) to meet study schedule**
- **Results will define dose(s)/infusion rates for upcoming Phase II single-dose UTI patient study**

Sydney Australia, 10 July 2023: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**), the Company developing a New Class of Synthetic Anti-Infectives, is pleased to announce its Phase I/II UTI clinical trial evaluating RECCE® 327 (R327) at faster infusion rates has successfully dosed its first cohort of both male and female subjects with **No Serious Adverse Events**.

The cohort were all dosed at two faster infusion rates of 2,500mg and included the first female to receive R327 via I.V. administration – more rapid than that used in the Company's completed 80 subject Phase I study. Assessments are being conducted to determine the effectiveness of R327's antibacterial activity in the urine of dosed participants.

Full details on the trial can be found on anzctr.gov.au under the Trial ID ACTRN12623000448640.

Non-Executive Director of Recce Pharmaceuticals and Recce's Medical Monitor of the Clinical Trial, Alan W Dunton, MD said: "In Recce's completed 80 subject Phase I study of R327 administered as a 1-hour infusion, data showed that R327 concentrated in the urine by at least 15-fold compared to plasma concentrations."

Dr Dunton continued "Peak concentrations of R327 in urine noted in this study have been shown *in vitro* in human urine to effectively kill *E. coli* within minutes, not hours as is seen for currently used and approved antibiotics for UTI treatment. It is estimated that more than 70% of UTI patients have bacteria in their urine, which are now resistant to two or more antibiotics[1]. Furthermore, UTI infections are the foundational contributor to more than 30% of sepsis cases globally[2]."

The Company believes the knowledge from this current study should raise the probability of R327 having a positive therapeutic effect against any bacteria (Gram-positive and/or Gram-negative, including ESKAPE pathogens) in patients in future studies.

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

[1] Ahmed SS, Shariq A, Alsalloom AA, Babikir IH, Alhomoud BN. Uropathogens and their antimicrobial resistance patterns: Relationship with urinary tract infections. Int J Health Sci (Qassim). 2019
2 Qiang XH, Yu TO, Li YN, Zhou LX. Prognosis Risk of Urosepsis in Critical Care Medicine: A Prospective Observational Study. Biomed Res Int. 2016

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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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