ASX Announcement

Recce Pharmaceuticals
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Update on Progress of Broad Spectrum Antibiotic RECCE® 327 Towards Clinical Trials

SYDNEY, Australia, 17 July 2018: Recce Pharmaceuticals Ltd (ASX:RCE) (**Company**), the Company developing a new class of synthetic, broad spectrum antibiotics, today provided an update on its progress towards the start of human trials of its lead compound RECCE® 327, for the treatment of sepsis, including a simple clinical trial design.

RECCE® 327 is being developed as a new class of antibiotic, designed to address the urgent global health issue of growing antibiotic resistance (superbugs). It was awarded Qualified Infectious Disease Product (QIDP) designation in late-2017, as part of the US *Generating Antibiotic Incentives Now (GAIN) Act*, labelling it for Fast Track Designation, plus 10 years of market exclusivity post approval.

Submission of its recent data package to the US Food & Drug Administration (FDA), and close interaction with the FDA facilitated by this designation, has enabled Recce in conjunction with its FDA advisory partners, to develop a simple protocol, subject to FDA approval, for a first-in-human Phase Ia clinical trial.

International clinical trial groups that may be involved in trials of RECCE® 327 are evaluating a proposed randomised, double-blind, placebo-controlled Phase Ia study which would seek to evaluate safety and tolerability in 44 adult participants given a single ascending dose of RECCE® 327, administered intravenously as an infusion, at a uniform rate over 24 hours under medical supervision. Reportable human data from the Phase Ia trial would be expected to be available within months of starting the study. Based on data from the Phase Ia study, an expanded Phase Ib study would soon follow. Both Phase Ia and Ib trial protocols are designed to be cost and time efficient, with both are expected to be completed within 12 months of the start of a Phase Ia study.

Since meeting with the FDA in May, Recce has continued its data driven focus, with the view to expanding the understanding of its new class of broad spectrum antibiotic technology that has been demonstrated to overcome the typical development of antibiotic resistance by bacteria exposed to traditional drugs.

Recce Pharmaceuticals Executive Chairman, Dr Graham Melrose said, “Our continued encouraging pre-clinical advancements support the current investigation into materialising a clinical protocol as we look ahead to substantiate our next stages of business.”

The Company will continue to update the investment community on material outcomes associated with its continued pre-clinical program in support of gaining approval for Phase I clinical trials.

About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE) is pioneering the development and commercialisation of a new class of synthetic antibiotics with broad spectrum activity designed to address the urgent global health problem of antibiotic resistant superbugs. Its patented lead candidate known as RECCE® 327 has been developed for the treatment of blood infections and sepsis derived from *E. coli* and *S. aureus* bacteria – including their superbug forms. Pre-clinical testing in laboratories and animal models, in Australia and overseas has demonstrated positive results. Recce has a manufacturing facility in Australia and is developing clinical research partners in the USA. The Company has developed an automated process to manufacture its lead compound ahead of first-in-human clinical trials.

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