Recce Pharmaceuticals
recce.com.au
ACN 124 849 065

ASX Announcement

FDA Positive Response for Recce Scaled Manufacture and Quality

Sydney, Australia, 26 August 2019: Recce Pharmaceuticals Ltd (ASX:RCE) (**Recce** or the **Company**), developing a New Class of Broad Spectrum antibiotics, today announced advances in scaled manufacture and drug quality following positive Food and Drug Administration (FDA) feedback to its Chemistry, Manufacturing, and Controls (CMC) data pack.

Recce's manufacture of its lead antibiotic compound RECCE® 327 has achieved a 500% increase in production and robust operational outputs that include internal/external validation of the following:

- 500 doses per automated manufacture output in less than 1 hour/run
- Raw material to finished product maintained at 99% yield
- Volume output at Clinical Phase I & II Scale levels with multiple runs within a range of <1% variability
- Quality Assurance/Controls (QA/C) to Good Laboratory Practice (GLP) standards
- 6-month product stability (shelf-life) at 2-8 degrees achieved with ongoing assessment
- Independent in-vitro efficacy protocol established and repeatable – Minimum Inhibitory Concentration against standardised *Staphylococcus aureus* & *Escherichia coli* bacteria
- Packaging and Labelling to international 'tamper-proof' clinical standards complete
- Leading Clinical Trial Logistics group contracted for handling all dispatch to delivery according to FDA requirements

Recce is in the positive position of receiving continuous feedback review from the FDA as RECCE® 327 has been awarded *Qualified Infectious Disease Product* (QIDP) designation, seeing the FDA prioritise review of data.

Recce will continue to evolve its Good Manufacturing Practice (GMP) capabilities at its wholly owned Macquarie Park manufacturing facility in Sydney, using Quality Controls consistent with guidelines for human clinical purposes.

Chairman Dr John Prendergast said, "We are very encouraged with this favourable review of our key chemistry and manufacturing data. Underpinned by Recce's unique method of synthesis and manufacture, our current manufacturing capability affords us the potential to achieve excellent economies of scale and reproducibility in terms of future commercial batches".

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. Recce antibiotics are unique – their potency does not diminish even with repeated use, which is a common failure associated with existing antibiotic use and the resulting emergence of resistant superbugs. Patented lead candidate RECCE® 327, wholly owned and manufactured in Australia, has been developed for the treatment of blood infections and sepsis derived from *E. coli* and *S. aureus* bacteria – including their superbug forms. 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. Recce wholly owns its automated

For further information please visit www.recce.com.au or contact:

Investor Relations
James Graham
Executive Director
Recce Pharmaceuticals Ltd
Tel: +61 (02) 8075 4585

Media (Australia)
Andrew Geddes
CityPR
Tel: +61 (02) 9267 4511

Media (International)
Sue Charles/Gemma Harris
Instinctif Partners
Tel: +44 (0)20 7866 7860
E: recce@instinctif.com

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.

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Sue Charles/Gemma Harris
Instinctif Partners
Tel: +44 (0)20 7866 7860
E: recce@instinctif.com