ASX Announcement

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US FDA Grants Qualified Infectious Disease Product Designation for RECCE® 327

SYDNEY Australia 16 November 2017: Recce Limited (ASX: RCE), an early stage pharmaceutical company developing a new class of synthetic antibiotics, today announced the US Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) designation for its lead compound RECCE® 327. This designation is an important achievement in the regulatory path for RECCE® 327 with the FDA and has significant benefits to the business.

Recce's application to the FDA is for RECCE® 327 as a broad spectrum antibiotic, used intravenously against *E.coli (Escherichia coli*) and Staph (*Staphylococcus aureus*) bacteria in the blood, including their superbug forms. These infections often lead to sepsis or 'blood poisoning' and are life threatening if untreated or if treatment isn't effective.

Through the grant of QIDP designation, RECCE® 327 is labeled for Fast Track designation which is designed to speed the FDA's review process and allows QIDP designated drugs that treat serious or life-threatening conditions and fill an unmet medical need, to be expedited for review in order to facilitate their development.

In addition, if RECCE® 327 completes the necessary clinical trials and is approved by the FDA, the QIDP designation will provide five years of market exclusivity, starting from the date of New Drug Application approval, extended for another five years through Hatch-Waxman exclusivity. Additional protection is provided by the Company's patents.

QIDP designation is part of the *US Generating Antibiotic Incentives Now (GAIN) Act* and was formed with the view to encourage development of new treatments for antibiotic-resistant organisms known to cause serious or life-threatening infections.

Recce's Executive Chairman Dr Graham Melrose said: "The fact that RECCE® 327 meets the FDA's criteria for Qualified Infectious Disease Product designation is a tremendous validation of our strategy to invest in synthetic polymers as potentially a whole new-class of antibiotics. This designation is an important step of the regulatory process, with RECCE® 327 clearly in the FDA's sight, and is well positioned to continue communications with them."

Announcing the positive news during World Antibiotic Resistance Awareness Week, when the urgent need for new antibiotics to address the rapidly emerging threat of superbugs is being highlighted, Dr Graham Melrose added: "Our plans for RECCE® 327 are on track to progress its development towards clinical testing in humans; we are encouraged that it has the potential to play an important role in the global challenge of antibiotic resistance."

About Recce Ltd

Recce Limited (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 to date. Recce has a manufacturing facility in Australia and clinical research partners in the USA. The Company has validated an automated process to manufacture its lead compound ahead of first-in-man clinical trials.

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

Investor Relations
Peter Williams
CFO & Company Secretary
Recce Ltd
Tel: +61 (08) 9253 9800

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