

ASX Announcement

Update on meeting with US FDA

SYDNEY, Australia, 16 May 2018: Recce Pharmaceuticals Ltd (ASX: RCE) (**Recce** or the **Company**), developing a new class of synthetic antibiotics, announces that on the 11th of May 2018 it met with the US Food and Drug Administration (FDA) as planned, to discuss the proposed clinical and regulatory pathway for its lead synthetic antibiotic compound RECCE[®] 327.

Representatives from the Company, in conjunction with its world leading FDA consultants Parexel International, met with the FDA's Division of Anti-Infective Products, Office of Antimicrobial Products which will provide formal written minutes including the action required by the Company to best facilitate its on-going antibiotic development program, within 30 days.

Recce Pharmaceuticals is seeking clinical and regulatory guidance for its lead compound RECCE[®] 327, which was granted Qualified Infectious Disease Product (QIDP) designation by the FDA late last year for the treatment of bacteraemia (sepsis)

QIDP designation is part of the *US Generating Antibiotic Incentives Now (GAIN) Act*, labelling RECCE[®] 327 for Fast Track designation, plus 10 years of market exclusivity post approval.



ASX: RCE

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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-man clinical trials.

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

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