

## Meeting with US FDA on Phase I Clinical Trial for RECCE 327 Antibiotic

**SYDNEY, Australia, 8 March 2018:** Recce Pharmaceuticals Ltd (ASX: RCE), the company developing a new class of synthetic antibiotics, today announced it has been invited to attend a face-to-face meeting with the US Food and Drug Administration (FDA) to discuss its unique technology and proposed clinical and regulatory pathway for its lead synthetic antibiotic compound RECCE® 327.

The meeting, scheduled for early May, is set to take place at the FDA headquarters in Washington DC USA and will include members of Recce's technical and manufacturing teams, its FDA consultants Parexel International and infectious disease representatives of the FDA.

The invitation is an outcome of Recce's recent additional technical data submission, which included a number of questions to the FDA relating to Recce's proposed regulatory pathway of RECCE® 327, including a Phase 1 clinical trial and beyond. This initiative has been made with the view to open communications with the US regulator as the company seeks to set the regulatory pathway in a clear and expedient direction.

Recce's lead compound RECCE® 327 was awarded Qualified Infectious Disease Product (QIDP) designation in late-2017, which provides a process to drug sponsors for expedited review and 10 years of market exclusivity post-approval for products that treat serious or life-threatening infections.

Executive Chairman Dr Graham Melrose said, "Given the urgent medical need for new antibiotics, in the face of rising incidence of drug resistant superbugs, we look forward to meeting with the FDA to explore the most efficient regulatory pathway for RECCE® 327".



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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.

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