

## ASX Release

### Data Submission & Further Communication Request with US FDA

**SYDNEY, Australia, 15 February 2018:** Recce Pharmaceuticals Ltd (ASX: RCE), the company developing a new class of synthetic antibiotics, today announced it has submitted additional data to the US Food and Drug Administration (FDA), including an additional communication request.

The additional data pack includes expanded pre-clinical data and a proposed Phase 1 clinical trial program for the company's lead compound RECCE® 327, a synthetic antibiotic for the treatment of sepsis derived from *Staphylococcus aureus* (*S. aureus*) and *Escherichia coli* (*E. coli*) – including their superbug forms.

The standard response time for submissions is 21 days.

The submission and request for communication leverages the unique opportunities gained through the fact that RECCE® 327 has Qualified Infectious Disease Product (QIDP) designation and forms key additions to the Company's overall Investigational New Drug (IND) application. The submission was made in conjunction with a leading regulatory and clinical research organisation (which has helped 95 per cent of the world's 200 top-selling pharmaceuticals).

Executive Chairman Dr Graham Melrose said, "Further communication with the FDA would be an opportunity to further support our new class of antibiotics as we seek to help address urgent human health needs".

#### 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



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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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For further information please visit [www.recce.com.au](http://www.recce.com.au) or contact:

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