ASX Announcement

Recce Pharmaceuticals
recce.com.au
ACN 124 849 065

Update on meeting with US FDA

- **13-member panel of FDA Division of Anti-Infective Products gives guidance at face-to-face meeting to advance lead compound RECCE® 327**
- **No issues, objections or concerns with data presented**

SYDNEY, Australia, 5 June 2018: Recce Pharmaceuticals Ltd (ASX: RCE) (**Recce** or the **Company**), developing a new class of synthetic antibiotics, today said it had received formal guidance following its meeting last month with the US Food & Drug Administration's Division of Anti-Infective Products, Office of Antimicrobial Products.

Recce was invited by the FDA to present its new class of antibiotic technology at the FDA's Silver Spring MD headquarters and discuss regulatory pathways in the US for its lead antibiotic compound RECCE® 327 aimed at addressing the urgent global health issue of growing antibiotic resistance (superbugs).

(Left to Right): ***Michele Dilizia*** *(Executive Director - Head of Regulatory Affairs & Microbiology),* ***Dr Graham Melrose*** *(Executive Chairman & Chief Research Officer),* ***Arthur Kollaras*** *(Principal Engineer) and* ***Dr Justin Ward*** *(Principal Quality Chemist) – FDA Head Quarters in Silver Spring MD*

With a data package provided by the Company and in conjunction with its FDA consultants Parexel International, the 13-member FDA panel was supportive, providing critical guidance covering chemistry, manufacturing, toxicology, pharmacology and design of proposed clinical trials.

The overarching message deals with RECCE® 327 as a new, innovative synthetic polymer-based compound, never-before seen in the world of pharmaceuticals and containing many active sites compared to the few with existing antibiotics.

The company received clear guidance around the design of a planned Phase I trial and steps to enhance the chemical analysis of the RECCE® 327's compound - with the view to clarity and understanding of its molecular structure, correlated with the efficacy repeatedly demonstrated to date and submit additional data with its planned application to start human clinical trials.

With no issues, objections or concerns to existing data raised and studies for the data requested now underway, these should be completed and ready for submission in the next several quarters.

Recce Executive Chairman Dr Graham Melrose said "We are greatly encouraged by the FDA's response to our new class of synthetic antibiotic. RECCE® 327's unique claim to overcome superbugs is certainly of urgent and global medical need, and we now have a clear pathway to achieve development of this drug accordingly".

Recce expects a substantial R&D rebate next month as already set aside as part of the Company's Advanced Finding with the Australian Government, thus speeding the return of funds. The Company will continue to manage its finances prudently to achieve the goals laid out in the FDA guidance.

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

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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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