

ASX Announcement

Recce Pharmaceuticals (ASX:RCE) Business Update

SYDNEY Australia, 16 December 2020: Recce Pharmaceuticals Ltd (**ASX: RCE**), the Company developing New Classes of Synthetic Anti-Infectives, is pleased to provide an update on its clinical programs.

Topical Phase I/II Human Clinical Trial Submission

Topical Phase I/II human clinical study is on track and progressing well. The Company recently announced it has received Human Research Ethics Approval for its Phase I/II human topical clinical trial in infected burn wounds and is closely working with South Metropolitan Health Service (Department of WA Health) on operational specifics with first patient treatment anticipated Q1 2021.

Intravenous Phase I Human Clinical Trial

Phase I clinical trial is progressing well with onsite audits this week and patient screening expected to take place in Q1 of 2021. The Company's lead product RECCE® 327 (R327) has been dispatched to clinical research facility CMAX in Adelaide, who have 30,000 registered patient volunteers on file.

Murdoch Children's Research Institute

Independent animal ethics committee has approved the first pre-clinical animal studies to assess potential of RECCE® 435 (R435) administered orally for the treatment of *Helicobacter pylori* (*H. pylori*) gastric infection, at Murdoch Children's Research Institute (MCRI). Samples of R435 have been received by MCRI, and the work being led by world *H. pylori* expert Professor Phil Sutton (Head of Mucosal Immunology at MCRI), is on track for first data to be reported in Q1 2021.

SARS-CoV-2 (COVID-19) Studies

During the current quarter, the Company received encouraging results from SARS-CoV-2 studies in both Australia and the United States, with each advancing to their respective next



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stages. In the United States, both R327 and RECCE[®] 529 (R529) compounds are in advanced stages of *in vivo* testing completion according to international COVID-19 study protocols in leading testing species of hamsters and ferrets.¹ The two gold-standard studies in COVID-19 testing allows for the assessment of various modes of administration to combat the disease.

The first of the hamster data via intranasal administration is expected within the next two weeks, with ferret animal data via other modes of administration expected to follow soon after.

Looking ahead

The Company's continues to manage a strong balance sheet in excess of \$23 million AUD (ex anticipated R&D in-flow) in support of its infectious disease activities and looks forward to updating investors over the time ahead.

This announcement has been approved for release by Recce Pharmaceuticals Board

¹ <https://www.nature.com/articles/s41586-020-2787-6>



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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE) is pioneering the development and commercialisation of New Classes of Synthetic Anti-Infectives designed to address the urgent global health problems of antibiotic resistant superbugs and emerging viral pathogens.

Recce's anti-infective pipeline is unique and comprised of broad-spectrum synthetic polymer antibiotics RECCE[®] 327 and RECCE[®] 435, and RECCE[®] 529 for viral infections with unique mechanisms of action against hyper-mutation on bacteria and viruses, respectively.

Patented lead candidate 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. Recce's new antibiotic compound, RECCE[®] 435, has been formulated for oral use.

The FDA has awarded RECCE[®] 327 *Qualified Infectious Disease Product* designation under the *Generating Antibiotic Initiatives Now* (GAIN) Act – labelling it for Fast Track Designation, plus 10 years of market exclusivity post approval.

Recce wholly owns its automated manufacturing, ready to support first-in-human clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of RECCE[®] technologies targeting synergistic, unmet medical needs.



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