

ASX Announcement

RECCE® 327 Progresses to Stage 2 of SARS-CoV-2 Antiviral Screening Program at CSIRO

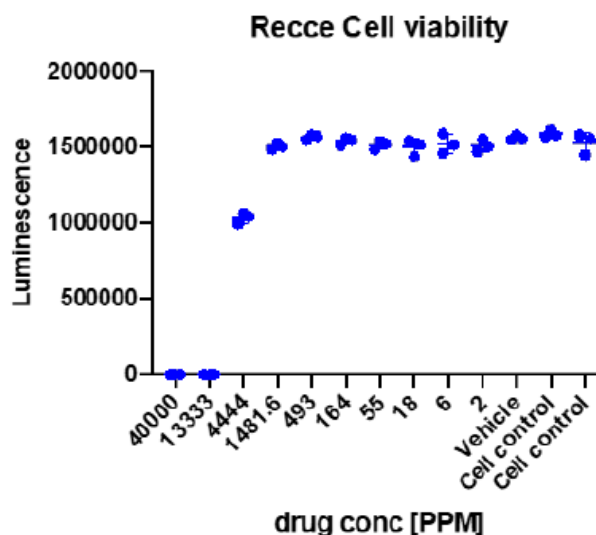
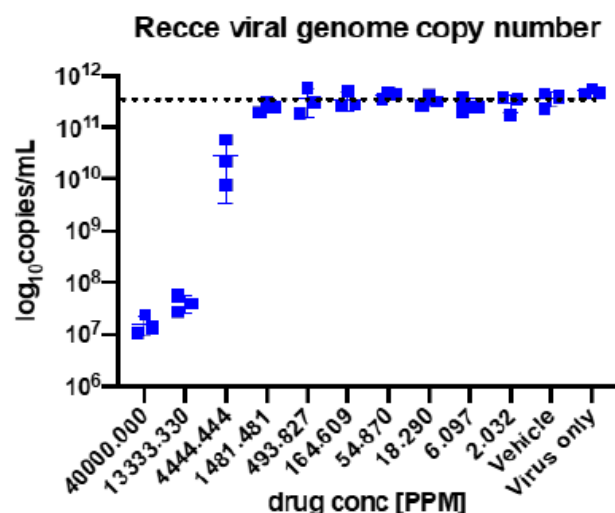
Summary:

- Further study completed at the Doherty Institute as part of SARS-CoV-2 Antiviral Screening Program (the Program), calculates IC50 of RECCE® 327 (R327) to be 2,046 PPM and the CC50 for R327 to be 5108 PPM
- R327 received a qualified recommendation to advance to Stage 2 of the Program for further testing to be conducted by the Commonwealth Scientific and Industrial Research Organisation (CSIRO)

Sydney Australia, 19 May 2021: Recce Pharmaceuticals Ltd (**ASX: RCE**) (**FSE:R9Q**) (**Company**), the Company developing New Classes of Synthetic Anti-Infectives, today announced further results for the Company's synthetic anti-infective R327, as part of the Program. The fee-for-service Program is being undertaken as a collaboration between CSIRO and the Doherty Institute.

The further Stage 1B testing which was highlighted as necessary in the Company's 12 February 2021 announcement has now been conducted by the Doherty Institute as part of the Program budget. The results confirmed and extended the findings from the previous report, announced 12 February 2021, and allowed the half maximal inhibitory concentration (IC50) of 2,046ppm and cytotoxicity (CC50) of 5,108ppm of R327 to be determined.

RECCE® 327 RT-PCR and Cell viability data



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High concentrations of R327 (13,333ppm and 40,000ppm) showed a 4-log reduction in SARS-CoV-2 viral genome numbers as measured by reverse transcription polymerase chain reaction (RT-PCR), but severe cellular toxicity was observed in vero cells at these concentrations. A half maximal Cytotoxic Concentration (CC50) of 5,108ppm was calculated for R327.

R327 reduced SARS-CoV-2 viral genome copy numbers at 4,444ppm and was accompanied by reduced infectious virus titres, allowing a half maximum Inhibitory Concentration (IC50) calculation of 2,046ppm. At 4,444ppm, R327 showed some toxicity, with a rounded cell morphology seen on microscopy.

Assays were repeated in triplicate and error bars are shown on the curves. The curves used to determine IC50s took this variation into account.

R327 has currently been shown to be effective and not highly toxic at a small window of concentrations in the preliminary in vitro testing in vero cells, and so received a qualified recommendation to proceed to Stage 2 of the Program for further testing in normal human bronchial epithelial (NHBE) cells grown at the air-liquid interface to be conducted by CSIRO, with anticipated results towards the end of the year.

Further testing must be completed in order to determine whether R327 will show an inhibitory effect against the SARS-CoV-2 virus without associated toxicity. All intellectual property rights are retained by the Company with data to be reported as it becomes available. The Company would like to thank the Doherty Institute for performing the experiments for Stages 1A and 1B of the Program and looks forward to working with the CSIRO team in relation to Stage 2 of the Program.

Non-Executive Chairman Dr. John Prendergast said, “These encouraging results continue to reinforce our confidence in the potential of R327 against SARS-CoV-2 as another line of defence in the arsenal against COVID-19. We are keen to continue our work with CSIRO in Stage 2 of the Anti-Viral Screening Program.”

This announcement has been approved for release by Recce Pharmaceuticals Board.



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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, 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. Further to this designation, RECCE® 327 has been included on The Pew Charitable Trusts *Global New Antibiotics in Development Pipeline* as the only synthetic polymer and sepsis drug candidate in development.

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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