

# **RECCE® 327 SARS-CoV-2 Study Update**

# Highlights:

- RECCE<sup>®</sup> 327 (R327) shown to significantly reduce SARS-CoV-2 in hamsters
- New Patents lodged supporting anti-infective capability in Brazil, Canada, China, Israel, India and Vietnam
- Australian SARS-CoV-2 studies concludes by mutual agreement

**SYDNEY Australia, 18 October 2022:** Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing a New Class of Synthetic Anti-infectives, is pleased to update on the findings in SARS-CoV-2 studies undertaken by an independent, third party contract research organisation (CRO).

The Company's engagement with the Netherlands based CRO, Viroclinics, has seen its SARS-CoV-2 studies demonstrate significant efficacious activity of R327 against the SARS-CoV-2 virus in Syrian golden hamsters – the gold-standard in COVID studies<sup>1</sup>. The goal of the study was to investigate the therapeutic efficacy of R327 administered via the intranasal route against the delta variant of SARS-CoV-2 in the hamster model. This route was chosen as SARS-CoV-2 infection is primarily located in the respiratory tract.



<sup>1</sup> https://www.criver.com/eureka/syrian-hamsters-starring-role-covid-19-research



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The study consisted of five groups of 12 hamsters infected intranasally with SARS-CoV-2 prior to being treated twice daily, with either a low (200 mg/kg), mid (400 mg/kg) or high (600 mg/kg) dose of R327. Treatment commenced four (4) hours after infection was initiated.

SARS-CoV-2 levels in infected animals were quantified using two techniques; gPCR (which measures viral genetic material and cannot distinguish between live and dead virus) and TCID50 (which measures live infectious viruses). Using these two different techniques, treatment with R327 was shown to significantly reduce SARS-CoV-2 levels in a dosedependent manner, in throat swab samples collected from these animals. This study provides proof-of-concept that intra-nasal treatment with R327 has the potential to reduce SARS-CoV-2 levels during infection. Recce is delighted by the results, but further testing must be completed before R327 is confirmed as being safe or effective against the SARS-CoV-2 virus, such as human clinical studies.

The Company has moved quickly to lodge further patent applications; with claims including, but not limited to:

- Composition/method of manufacture of RECCE anti-infectives •
- Use of R327 or R529 for the treatment of viruses having a lipid envelope or • coat, examples being SARS-CoV-2 and Corona viruses, Influenza viruses, HIV, Hepatitis, Ross River and Herpes viruses
- Administration of R327 or R529 by oral, injection, inhalation and transdermal • dose applications

On 8 July 2020 the Company announced that investigations into the efficacy of R327 had commenced. In those investigations conducted by the CSIRO, R327 did not fulfill the agreed criteria required for the CSIRO to commence *in-vivo* animal testing (in ferrets). Accordingly, the Company and CSIRO have discontinued investigations related to R327 and the Company thanks CSIRO for its assistance.

In light of the positive in-vivo study results from the Netherlands COVID in-vivo hamster study, the Company will consolidate its focus to anti-viral (COVID) studies overseas.

Recce Pharmaceuticals Chief Executive Officer James Graham said, "The data received from Viroclinics indicates the potential of R327's capabilities as a treatment for viral



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infections. Conducting our SARS-CoV-2 study in the Netherlands reaffirms the Company's intention to address the ongoing effects that Europe has experienced throughout the pandemic."

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



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## About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: **RCE**, FSE: **R9Q**) is developing a New Class 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 includes three patented, broad-spectrum, synthetic polymer anti-infectives: RECCE<sup>®</sup> 327 as an intravenous and topical therapy that is being developed for the treatment of serious and potentially life-threatening infections due to Gram-positive and Gram-negative bacteria including their superbug forms; RECCE<sup>®</sup> 435 as an orally administered therapy for bacterial infections; and RECCE<sup>®</sup> 529 for viral infections. Through their multi-layered mechanisms of action, Recce's anti-infectives have the potential to overcome the hypercellular mutation of bacteria and viruses – the challenge of all existing antibiotics to date.

The FDA has awarded RECCE<sup>®</sup> 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<sup>®</sup> 327 has been included on The Pew Charitable Trusts Global New Antibiotics in Development Pipeline as the world's only synthetic polymer and sepsis drug candidate in development. RECCE<sup>®</sup> 327 is not yet market approved for use in humans with further clinical testing required to fully evaluate safety and efficacy.

Recce wholly owns its automated manufacturing, which is supporting present clinical trials. Recce's antiinfective pipeline seeks to exploit the unique capabilities of its technologies targeting synergistic, unmet medical needs.



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