Recce Pharmaceuticals
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ASX Announcement

Positive Sinusitis Patient Update - Special Access Scheme

Highlights:

- **RECCE® 327 (R327) delivers positive human clinical response against multidrug-resistant, Gram-negative *P. aeruginosa* sinusitis infection, in a single patient use pursuant to the TGA Special Access Scheme Category A (SAS - Category A)**
- **The patient outcome follows positive results from animal study in sinusitis with Gram-positive bacteria and supports broad spectrum potential of Recce's anti-infective compounds against life-threatening bacteria**

Sydney Australia, 7 April 2021: Recce Pharmaceuticals Ltd (**ASX:RCE, FSE:R9Q**) (**Company**), the Company developing New Classes of Synthetic Anti-Infectives, is pleased to announce that a Special Access Scheme (SAS) Category A notification has been made to the Therapeutic Goods Administration (TGA) by a medical practitioner following the successful treatment of a patient with RECCE® 327 (R327), via nasal passage, against multidrug-resistant *Pseudomonas aeruginosa (P. aeruginosa)* sinusitis infection.

While the Company is pleased with the apparent success of the application of R327, it is important to note that only a single patient has been treated pursuant to the Special Access Scheme, which is a notification pathway which can be accessed by health practitioners on behalf of a prescribing medical practitioner for patients who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment, and does not constitute a clinical trial.

R327 is not approved for use in humans and significant further clinical testing is required to evaluate the quality, safety and efficacy of R327.

Patient outcome (*P. aeruginosa* sinusitis) – Special Access Scheme Category A

As stated above, R327 was not applied as part of a clinical trial. Results must therefore be considered anecdotal, however, the Company is encouraged by them.

A 59-year-old male was categorised as suffering multidrug-resistant *P. aeruginosa* sinusitis infection. Clinical samples of R327 were released under strict medical oversight having been determined to meet TGA SAS-A criteria, including: 'seriously ill, where death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.'[1]

The patient has suffered from sinusitis infections all of their adult life, which had advanced to a multidrug-resistant Gram-negative *P. aeruginosa* sinusitis infection in their upper nasal eustachian tube. This infection was unresponsive to previous surgeries, all antibiotic treatments attempted including ciproflaxin (negative side effects), Septrim Forte (twice daily) and Doxylin, including last-resort peripherally inserted central catheter (PICC Line) methods of administration in some instances.

Patient X (for reasons of patient confidentiality) dosed according to a strict, dose-escalating protocol applying 5 -10 drops per 20 millilitres of R327 in saline solution, three times a day into the infected area. Using a rubber bulb, Patient X pushed the mixture up into both the left and right nasal passages, toward the ears. Upon applying R327 in the infected area, Patient X noted a minor stinging sensation as the solution reached the area of infection in both nasal passages, subsiding after approximately three minutes.

Within 90 minutes, Patient X recorded their sinuses began to feel clearer, less inflamed and reported less discharge. As Patient X continued their dosing program, it was recorded the stinging sensation subsided over time. Over a three-day period of applying R327 topically via spray to the infected areas in the sinus', Patient X reported a substantial reduction in infected discharge, termination of sweating and a return to normal sleeping patterns with no side effects. Post-dosing program, blood samples were taken and tested. These samples showed ***no detectable signs of P. aeruginosa infection and no abnormalities.***

Not long after the dosing program, the patient reported feeling a return of the initial infection. Following a sinus biopsy, an opportunistic 'common bacterium' had taken residence where the *P. aeruginosa* was previously. Having advanced from a life-threating infection status, it was agreed that the new, unrelated bacterial infection was early in its growth. A course of Septrim Forte cleared the opportunistic bacteria and the initial drug resistant *P. aeruginosa*

[1] https://www.tga.gov.au/book-page/information-health-practitioners

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remained undetected.

The Company is encouraged by the nasally administrated response of this patient and the formal submission to the TGA of the Special Access Scheme treatment, following its completion. The Company will continue with its clinical trials to assess the safety or efficacy of R327 and/or any related compounds.

James Graham, Chief Executive Officer of Recce Pharmaceuticals said, “We are thrilled by this positive indication for this patient with a terribly, debilitating condition that has been driven over many years by this recalcitrant pathogen.”

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 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 drug candidate for treating sepsis currently 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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