ASX Announcement

Recce Pharmaceuticals
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ACN 124 849 065

Murdoch Children's Research Institute - RECCE® 435 Against *Helicobacter pylori* stomach bacteria

Highlights:

- **Murdoch Children's Research Institute to evaluate the *in-vivo* antimicrobial activity of RECCE® 435 oral formulation against *Helicobacter pylori (H. pylori)* in pre-clinical studies program**
- **Studies led by *H. pylori* infectious disease expert Professor Philip Sutton**
- **Multiple world-first data opportunities over 12 months study program – anticipated human clinical trial beyond**

Sydney Australia, 30 September 2020: Recce Pharmaceuticals Ltd (**ASX: RCE**), the Company developing New Classes of Synthetic Anti-infectives, today announced it has entered into an agreement with the Murdoch Children's Research Institute (MCRI) to conduct pre-clinical studies assessing the potential of RECCE® 435 (R435) for the treatment of *Helicobacter pylori (H. pylori)* infections.

The research program will be carried out by the Mucosal Immunology Group at the MCRI, Royal Children's Hospital. The MCRI is the largest child health research institute in Australia and one of the top three worldwide for research quality and impact.[1]

Researchers will evaluate the antimicrobial activity of RECCE® 435 against *H. pylori* across a range of internationally recognised *in-vitro* & *in-vivo* study models. The studies will be led by Professor Philip Sutton, Head of MCRI Mucosal Immunology Group in Victoria, Australia. Professor Sutton recently joined Recce's clinical advisory committee as Head of the *H. pylori* program with a world leading background in the biology of *H. pylori* and the subsequent infections linked to stomach ulcers and gastric cancer.

There is a global unmet medical need for the treatment of *H. pylori* with no first-line therapy curative in all patients.[2] Today, the most commonly used treatment is triple therapy, which includes the use of a Protein Pump Inhibitor in combination with multiple

[1] https://www.mcri.edu.au/about
[2] https://www.racgp.org.au/afp/2014/may/helicobacter-pylori-eradication/

antibiotics (amoxicillin, metronidazole and/or clarithromycin).[3] The existing treatment duration is 7 to 14 days; however, the **eradication rate of standard triple therapy has fallen below 80%** due to the increasing prevalence of antibiotic resistant strains worldwide.[2]

Recce Non-Executive Chairman, Dr. John Prendergast states, "Antibiotic-resistant forms of *H. pylori* are on the rise. This is worrisome because more than four billion worldwide are infected with *H. pylori*[4], which is the leading cause of peptic ulcers and stomach cancer. We are excited to collaborate with Professor Sutton and MCRI in investigating the potential of our oral anbitiotic RECCE® 435 as what could be the first non-combination treatment for *H. pylori* infection, including those caused by drug resistant forms of the pathogen."

Recce and MCRI will work together on the oral antibiotic dosing program with a particular focus on optimal dosing and the effect of RECCE® 435. The agreement is in place until 31 December 2022; however, the Company anticipates completion in approximately 12 months, at which time it will pursue a human clinical trial. The Company is well funded to support the study program following its recent successful capital raise. All intellectual property rights are retained by the Company.

The World Health Organisation (WHO) lists *H. pylori* as a priority pathogen on its list of antibiotic-resistant bacteria that pose the greatest threat to human health. An expert led panel at the WHO identified that there is an urgent need to developnew antibiotics against *H. pylori*, which remains a significant cause of morbidity and mortality worldwide. As a result, The U.S. Food and Drug Administration have included *H. pylori* as a bacterium qualifying for their Qualified Infectious Disease Product (QIDP) programme. The estimated direct and indirect costs related to *H. pylori* and peptic ulcer disease is nearly $6 billion annually.[5]

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

[3] https://clinicaltrials.gov/ct2/show/NCT03832465
[4] https://www.gastrojournal.org/article/S0016-5085(17)35531-2/pdf
[5] https://www.cdc.gov/mmwr/preview/mmwrhtml/00049679.htm

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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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