ASX Announcement

Recce
Targeting Superbugs
recce.com.au
ACN 124 849 065

Recce Confirms Delivery by Intravenous Drip for its RECCE® 327 Antibiotic, with FDA IND Submission on Track

Key Points

- Positive data from additional pre-clinical studies confirm RECCE® 327 is equally effective in killing Gram positive and Gram negative bacteria and their superbug forms
- Therapeutic window for action of RECCE® 327 confirms administration via an IV drip as preferred mode of delivery
- Independent experts review Recce's draft IND and recommend proceeding to a pre-IND meeting with the US FDA prior to the document's final submission

SYDNEY Australia 31 July 2017: Recce Limited (ASX: RCE), a pre-clinical stage pharmaceutical company engaged in the development of a new class of synthetic antibiotics, today confirmed it remains on track to submit its Investigative New Drug Application (IND) to the US Food and Drug Administration (FDA) for its lead compound RECCE® 327, following additional positive pre-clinical study data on mode of administration, drug clearance, dosing and efficacy.

The first additional study, critical for FDA purposes, assessed how long RECCE® 327 antibiotic remained present in the blood of two species of animals, following administration via an intravenous (IV) infusion (drip), in order to kill pathogenic bacteria. In both small and large species animal models the data demonstrated that RECCE® 327 rapidly clears from the blood stream within a few hours. These data support that RECCE® 327 may be administered into the blood intravenously where it remains in the system long enough to kill pathogenic bacteria before being cleared.

A second additional study compared this valuable dose clearing data with the minimum dose required for *in-vitro* efficacy during 24 hours at acceptable toxicity. These data indicate that for RECCE 327®'s primary bacterial targets Staph (*Staphylococcus aureus*) and *E.coli* (*Escherichia coli*), the maximum tolerated dose that could be administered without observing excessive toxicity was 17-fold and 7-fold overdose, respectively. Furthermore, the findings

strongly suggest that administration by intravenous infusion would be even more efficient, since in this technique, dosing could be maintained at optimum levels over the 24 hours, versus single or intermittent dosing methods.

Recce completed the first draft of its IND application, including data from these two recent *in vitro* and *in vivo* studies and submitted it for independent review by two groups of expert regulatory consultants in the USA who have completed their reviews and will guide us during the planned meeting with the US FDA.

Recce confirms that it is on track during August to request the meeting with the FDA with a view to starting its first human trials.

Recce Executive Director and Head of Regulatory Affairs/Microbiology, Michele Dilizia, who has been leading the pre-clinical testing and IND preparation, said: “We have now concluded an intensive period of *in vitro* and *in vivo* studies to prepare our application to move RECCE® 327 into human clinical trials in the USA. The constructive feedback from the highly experienced regulatory experts will assist us to forward a favourable data package for our IND application to the FDA.”

Recce Executive Chairman Dr Graham Melrose, said: “In the antibiotics arena where new drugs with completely novel modes of action are so urgently needed to address the ever increasing problem of drug resistance, our achievements to date are encouraging not only for our investors, but also for patients and the healthcare community as a whole.”

About Recce Ltd

Recce Ltd (ASX: RCE) is a world-leader in synthetic-polymer compounds, particularly against all bacteria, and viruses. The RECCE® polymers have been synthesized by an extremely economic method. RECCE® polymers have shown in laboratory tests that they have continued activity against bacteria, including superbugs, even after repeated use. Recce has achieved milestones in both pre-clinical trials for FDA purposes, and the development of the manufacture of RECCE® 327. Recce has granted patents in Australia, United States, Europe, Japan and China – giving it legal monopolies, and potential financial returns, from manufacture and distribution of its products in about 80% of the world’s pharmaceutical markets for antibiotics.

To receive the latest information on Recce - Subscribe here

For further information please visit www.recce.com.au or contact:

Investor Relations
Peter Williams
CFO & Company Secretary
Recce Ltd
Tel: +61 (08) 9253 9800

Media (Australia)
Andrew Geddes
CityPR
Tel: +61 (02) 9267 4511

Media (International)
Sue Charles/Gemma Harris
Instinctif Partners
Tel: +44 (0)20 7866 7860
E: recce@instinctif.com

Appendix – Supporting data

Small & large species average concentration (%) of RECCE® 327 in blood plasma

AVERAGE CONCENTRATION (%) OF RECCE 327 IN RATS
(N = 6 rats / dose group)

1-Hour Intravenous Infusion

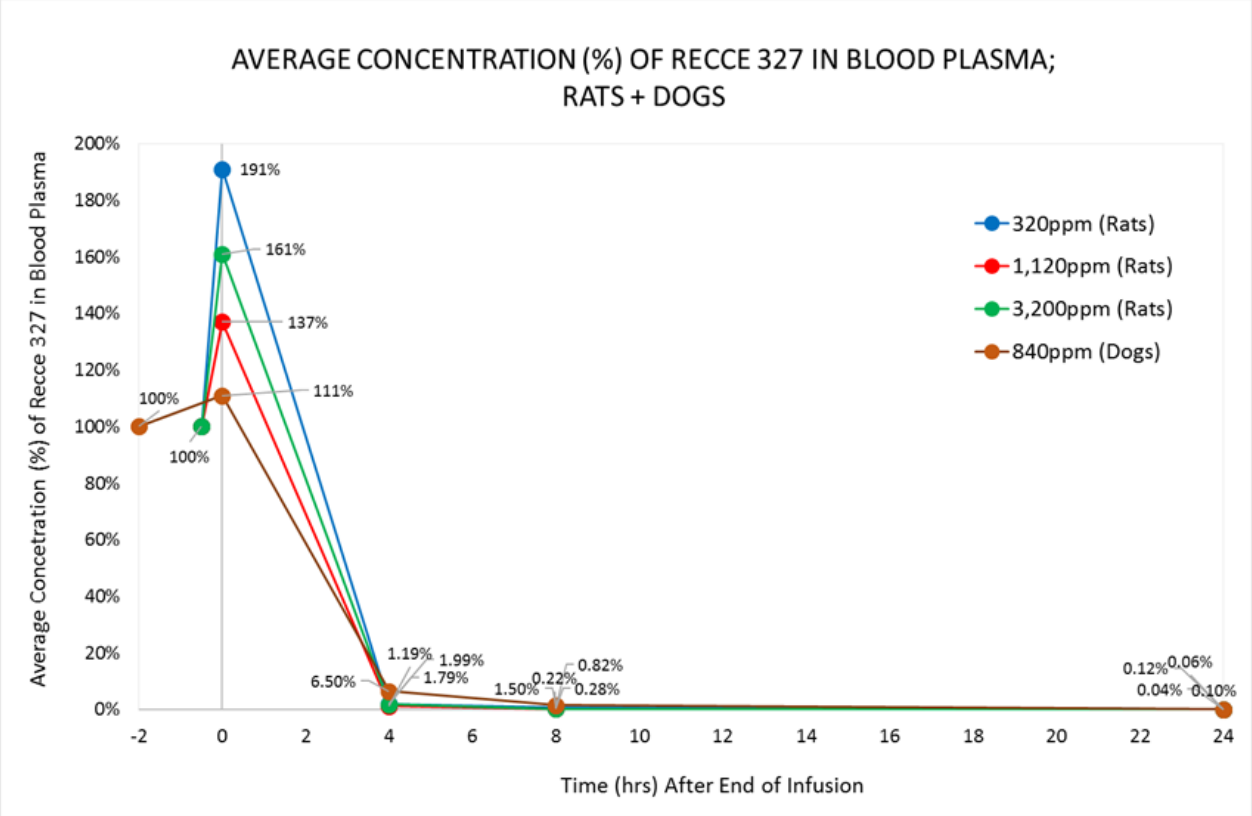
TIME	20mg/kg	70mg/kg	200mg/kg
30 minutes (half-way through infusion)	100 *	100 *	100 *
60 minutes (end of infusion)	191	137	161
4 hours (after end of infusion)	1.99	1.19	1.79
8 hours (after end of infusion)	0.82	0.22	0.28
24 hours (after end of infusion)	0.12	0.06	0.04

* First observation = 100%

AVERAGE CONCENTRATION (%) OF RECCE 327 IN DOGS
(N = 3 dogs / dose group)

TIME	70mg/kg
2 hours (half-way through infusion)	100 *
4 hours (end of infusion)	111
4 hours (after end of infusion)	6.5
8 hours (after end of infusion)	1.5
24 hours (after end of infusion)	0.1

* First observation = 100%



MKC/MIC STUDIES (ppm)

The method is to 2-fold dilute the sample of RECCE 327 until a concentration is found at which the concentration of antibiotic is unable to kill/inhibit the respective germs over a period of 24 hours. As the dilutions are 2-fold, the method is only accurate to the nearest 2-fold concentration, e.g. 500ppm & 1000ppm as shown are "equal".

	STANDARD BACTERIA	SUPERBUG BACTERIA
MINIMUM KILL CONCENTRATION OF RECCE 327 (ppm)		
Method using Broth Medium		
Gram Positive Bacteria		
Staphylococcus aureus	-	**180**
Enterococcus faecium	-	**450**
Gram Negative Bacteria		
Escherichia coli	**250**	**450**
Pseudomonas aeruginosa	**900**	
MINIMUM INHIBITORY CONCENTRATION OF RECCE 327 (ppm)		
Method using Broth Medium		
Gram Positive Bacteria		
Staphylococcus aureus	**250**	**250**
Gram Negative Bacteria		
Escherichia coli	**500**	**1,000**
Pseudomonas aeruginosa		
MINIMUM INHIBITORY CONCENTRATION OF RECCE 327 (ppm)		
Method using Minimal Glucose Medium		
Gram Positive Bacteria		
Staphylococcus aureus	**20**	**10**
Gram Negative Bacteria		
Escherichia coli	**60**	**120**
Pseudomonas aeruginosa	**250**	-