ASX Announcement

Recce Pharmaceuticals
recce.com.au
ACN 124 849 065

Positive Data on Bactericidal Activity of RECCE® 327 Against All Six ESKAPE Pathogens

Highlights:

- **More than 99.9% effective against full suite of ESKAPE pathogens, within hours of exposure to RECCE® 327 (R327) in independent bacterial efficacy studies**
- **R327 remains effective against hypermutated ESKAPE superbugs, including Multi-Drug Resistant (MDR) forms - a current market challenge of all existing antibiotics**
- **On-track to be the only company developing an efficacious anti-infective against ESKAPE pathogens globally**

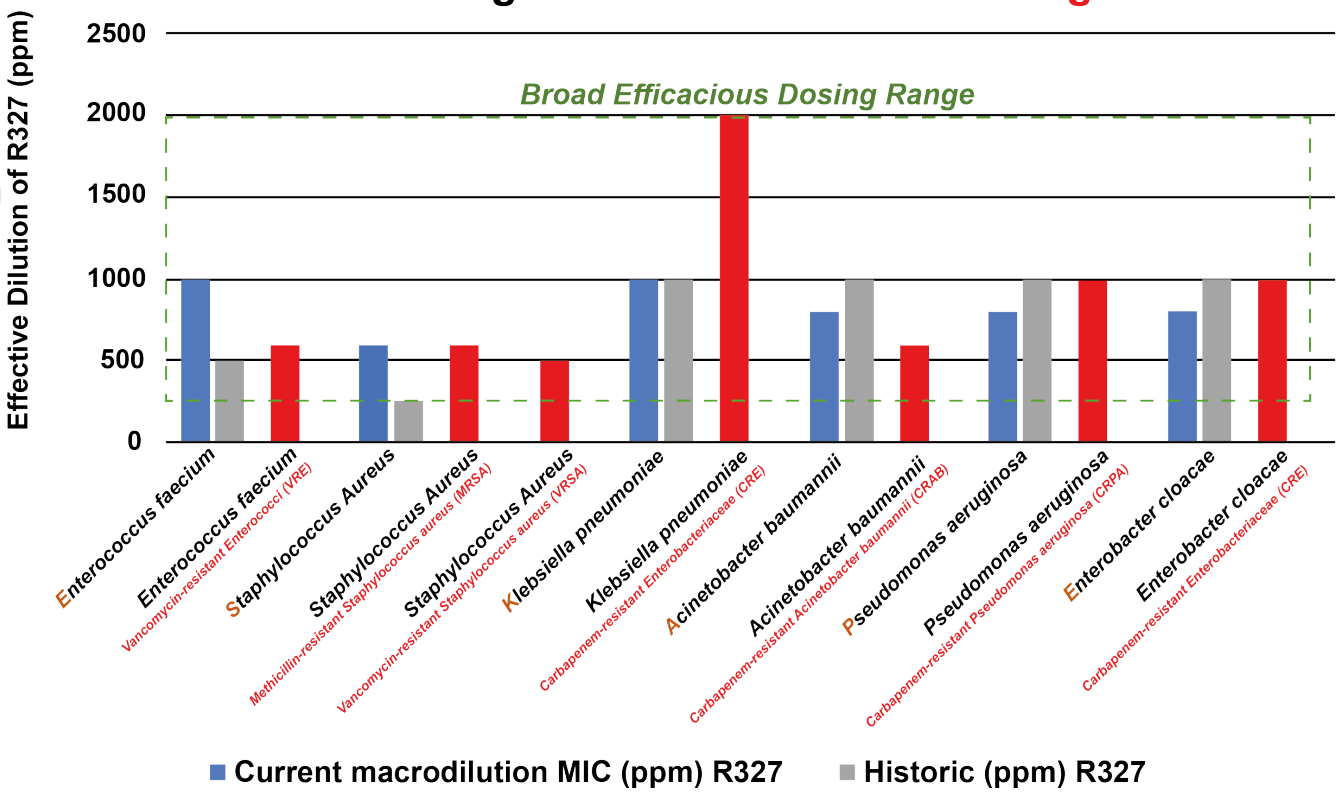
Sydney Australia, 4 May 2021: Recce Pharmaceuticals Ltd (**ASX:RCE**) (**FSE:R9Q**) (**Company**), the Company developing New Classes of Synthetic Anti-infectives, is pleased to announce RECCE® 327 (R327) has demonstrated bactericidal activity against all six antibiotic resistant ESKAPE pathogens, including drug resistant mutations (superbugs) as well as two additional World Health Organisation (WHO) priority pathogens list.

These antibiotic resistant bacteria acronymically dubbed 'ESKAPE' due to their propensity of 'escaping' the biocidal action of antibiotics, are collectively responsible for over 720,000 hospital acquired (nosocomial) infections in the United States alone each year.[1] The ESKAPE pathogens include both Gram-positive and Gram-negative bacteria; ***E**nterococcus faecium*, ***S**taphylococcus aureus*, ***K**lebsiella pneumoniae*, ***A**cinetobacter baumannii*, ***P**seudomonas aeruginosa*, and ***E**nterobacter* species.

The study was conducted by an independent Contract Research Organisation to assess the *in-vitro* efficacy of R327 against all ESKAPE pathogen bacterial strains. R327 is a broad-spectrum synthetic anti-infective that has potential to address the urgent global health threat posed by antibiotic resistant superbugs and emerging viral pathogens.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4871955/#:~:text=The%20ESKAPE%20pathogens%20(Enterococcus%20faecium,nosocomial%20infections%20throughout%20the%20world.

ESKAPE Pathogens: Standardised and Drug Resistant



No.	Species	Strain ID	Strain Information	Current macrodilution MIC (ppm) R327	Historic (ppm) R327
1	*Enterococcus faecium*	ATCC 19434	---	1000	500
2	*Enterococcus faecium*	ATCC 700221	VanA, VRE	600	---
3	*Staphylococcus aureus*	ATCC 29213	CLSI QC strain	600	250
4	*Staphylococcus aureus*	BAA-1556	USA300, MRSA	600	---
5	*Staphylococcus aureus*	VRS-2	VanA, VRSA	500	---
6	*Klebsiella pneumoniae*	ATCC 43816	Susceptible	1000	1000
7	*Klebsiella pneumoniae*	BAA-1705	CRE	2000	---
8	*Acinetobacter baumannii*	ATCC 17978	Susceptible	800	1000
9	*Acinetobacter baumannii*	FDA-CDC AR-BANK#0088	CRAB	600	---
10	*Pseudomonas aeruginosa*	ATCC 27853	CLSI QC strain	800	1000
11	*Pseudomonas aeruginosa*	FDA-CDC AR-BANK#0103	CRPA	1000	---
12	*Enterobacter cloacae*	ATCC 13047	---	800	1000
13	*Enterobacter cloacae*	FDA-CDC AR-BANK#0365	CRE	1000	---
14	*Enterococcus faecium*	ATCC 19434	---	1000	500
15	*Enterococcus faecium*	ATCC 700221	VanA, VRE	600	---
16	*Neisseria gonorrhoeae*	FA1090, ATCC 700825	Susceptible	300	---
17	*Neisseria gonorrhoeae*	WHO-L, CCUG 57598	MDR strain	500	---

Multi-Drug Resistant	
CRE	carbapenem-resistant *Enterobacteriaceae*
CRAB	carbapenem-resistant *Acinetobacter baumannii*
CRPA	carbapenem-resistant *Pseudomonas aeruginosa*
MRSA	methicillin-resistant *Staphylococcus aureus*
VRSA	vancomycin-resistant *Staphylococcus aureus*
VRE	vancomycin-resistant *Enterococci*

ESKAPE pathogens are responsible for 42.2% of blood infections,[2] around 50 million infections each year, resulting in one in five deaths in the community or one in three deaths in hospitals[3] and are associated with higher lengths of stay, cost of care, and mortality compared with non-ESKAPE pathogens[2].

The dilution method of R327 used in these studies slightly increased the Minimum Inhibitory Concentration (MIC) across the wide range of Gram-positive, Gram-negative and superbug forms of bacteria. The slight variation (+/-) between one experiment to the next is likely due to small variance in the sensitivity of the instruments used in detection. The dilution of R327 that showed efficacy against

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6902016/
[3] https://www.sensium.co.uk/news/lancet-publication-finds-one-in-five-deaths-due-to-sepsis/

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
+61 (02) 9256 2571
james.graham@recce.com.au

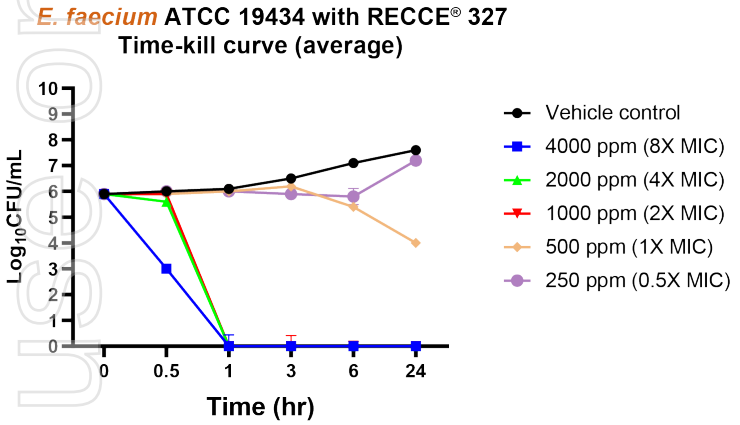
Media and Investor Relations (AU)
Andrew Geddes
CityPR
+61 (02) 9267 4511
ageddes@citypublicrelations.com.au

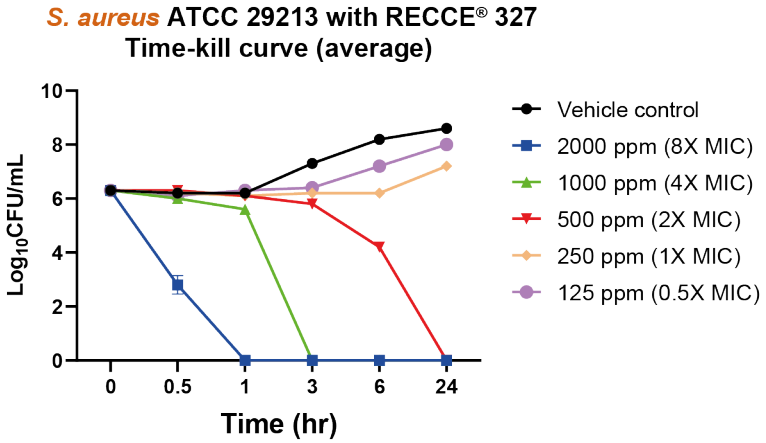
Media and Investor Relations (USA)
Meredith Sosulski, PhD
LifeSci Communications
+1 929 469 3851
msosulski@lifescicomms.com

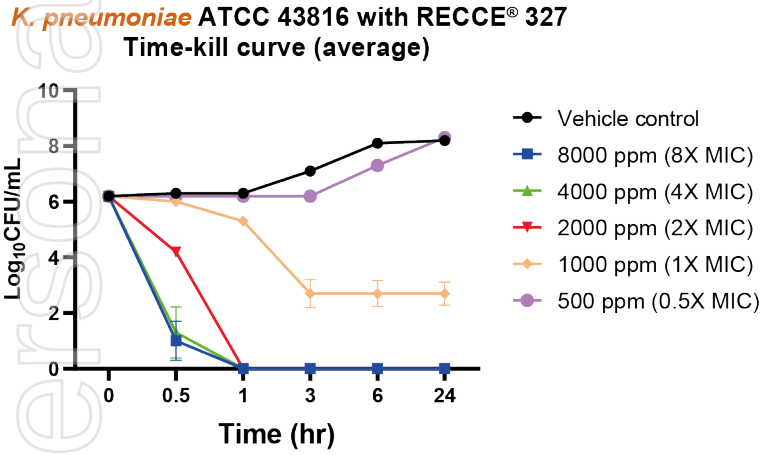
recce.com.au
ACN 124 849 065

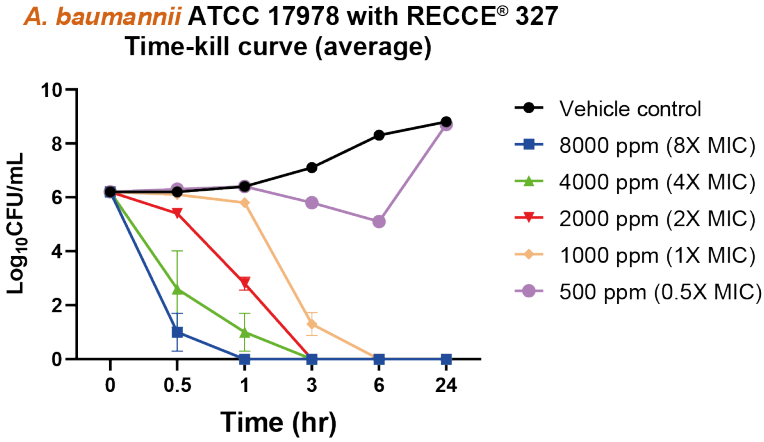
K. pneumonia (CRE) is higher than previous findings though still well within the therapeutic window dosing range.

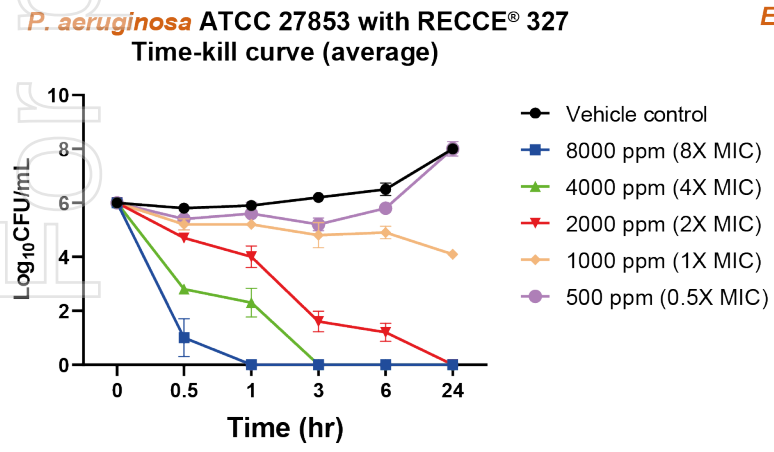
Additionally, R327 was shown to be effective against the WHO global priority pathogens carbapenem-resistant *Escherichia coli* (*E. coli* CRE) and multi drug resistant *Neisseria gonorrhoeae*[4] (*N. gonorrhea* MDR). These bacteria are listed on the WHO's list of priority pathogens as those for which new antibiotics are urgently needed in addition to ESKAPE pathogens.

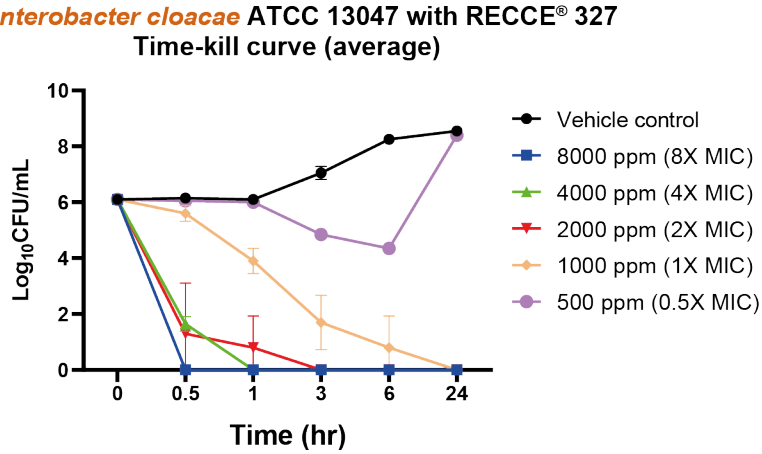












[4] https://www.pharmacologydiscoveryservices.com/catalogmanagement/viewitem/Neisseria-gonorrhoeae-MDR-WHO-L-CCUG-57598-MIC/612505

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
+61 (02) 9256 2571
james.graham@recce.com.au

Media and Investor Relations (AU)
Andrew Geddes
CityPR
+61 (02) 9267 4511
ageddes@citypublicrelations.com.au

Media and Investor Relations (USA)
Meredith Sosulski, PhD
LifeSci Communications
+1 929 469 3851
msosulski@lifescicomms.com

The minimum inhibitory concentration (MIC), or the lowest concentration of a drug that prevents visible growth of a bacterium or bacteria, was first determined to define the test concentrations for the time-kill study. The time-kill study was performed to determine the bacterial killing effect of R327 at a total of five concentrations, ranging from 0.5X to 8X the MIC and to measure killing kinetics of treatment with R327 against each strain.

Time-kill curves of R327 at various concentrations against strains of ESKAPE pathogens. In the time kill assay, each R327 dilution was tested in duplicate with the average plot shown.

The bactericidal activity of R327 demonstrated a **three-log or 99.9% reduction** in the number of colony forming units (CFUs) **over 24 hours** against all six strains at various concentrations and times.

Additional time kill concentration studies are underway with drug-resistant bacterial and are expected to be in-line with existing MIC/Time Kill. Data is expected in around a month and as pivotal inclusion in a Whitepaper/Abstract for presentation at the World Microbe Forum (20-24 June 2021) [5].

Recce Pharmaceuticals CEO James Graham said, "We are encouraged by the data from this study and will continue to explore the potential of RECCE® 327 to treat hospital-acquired infections. Antimicrobial resistance is one of the most urgent threats to global public health with the suite of ESKAPE pathogens posing a significant threat due to their virulence and rapid development of drug-resistance. Additionally, with R327 effective against two more priority pathogens listed by the WHO, we believe reinforces the potential of R327 to treat some of the greatest threats to human health."

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

[5] https://www.worldmicrobeforum.org/

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
+61 (02) 9256 2571
james.graham@recce.com.au

Media and Investor Relations (AU)
Andrew Geddes
CityPR
+61 (02) 9267 4511
ageddes@citypublicrelations.com.au

Media and Investor Relations (USA)
Meredith Sosulski, PhD
LifeSci Communications
+1 929 469 3851
msosulski@lifescicomms.com

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.

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
+61 (02) 9256 2571
james.graham@recce.com.au

Media and Investor Relations (AU)
Andrew Geddes
CityPR
+61 (02) 9267 4511
ageddes@citypublicrelations.com.au

Media and Investor Relations (USA)
Meredith Sosulski, PhD
LifeSci Communications
+1 929 469 3851
msosulski@lifescicomms.com