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Recce Pharmaceuticals Releases White Paper Providing Data and Market Positioning of its Synthetic Polymer Antibiotics

SYDNEY Australia, 23 October 2019: Recce Pharmaceuticals Ltd (ASX: RCE) (**Company**), the company developing a new class of antibiotics, today published a white paper providing pre-clinical and experimental data on its new synthetic antibiotics and outlining the market need, its anticipated market positioning and development strategy .

The paper titled "*How Synthetic Antibiotic Development Can Change the Antibiotic Treatment Model"* has been distributed ahead of the World Anti-Microbial Resistance Congress to be held on Thursday 7 to Friday 8 November in Washington D.C, where Recce Chairman Dr. John Prendergast will give the Opening R&D Address.

A copy of the paper is available below or can be downloaded here.

The paper highlights how the need for new antibiotics has never been greater as resistance has developed to most currently approved antibiotics. It examines the significant potential of Recce's promising synthetic antibiotic pipeline and potential role helping turn back the rising tide of antibiotic resistance globally. It presents data to support its potential as a life-saving antibiotic therapy, in particular for its lead application in sepsis.

A copy of Dr. John Prendergast's presentation will be released to the ASX immediately prior to the conference in November.

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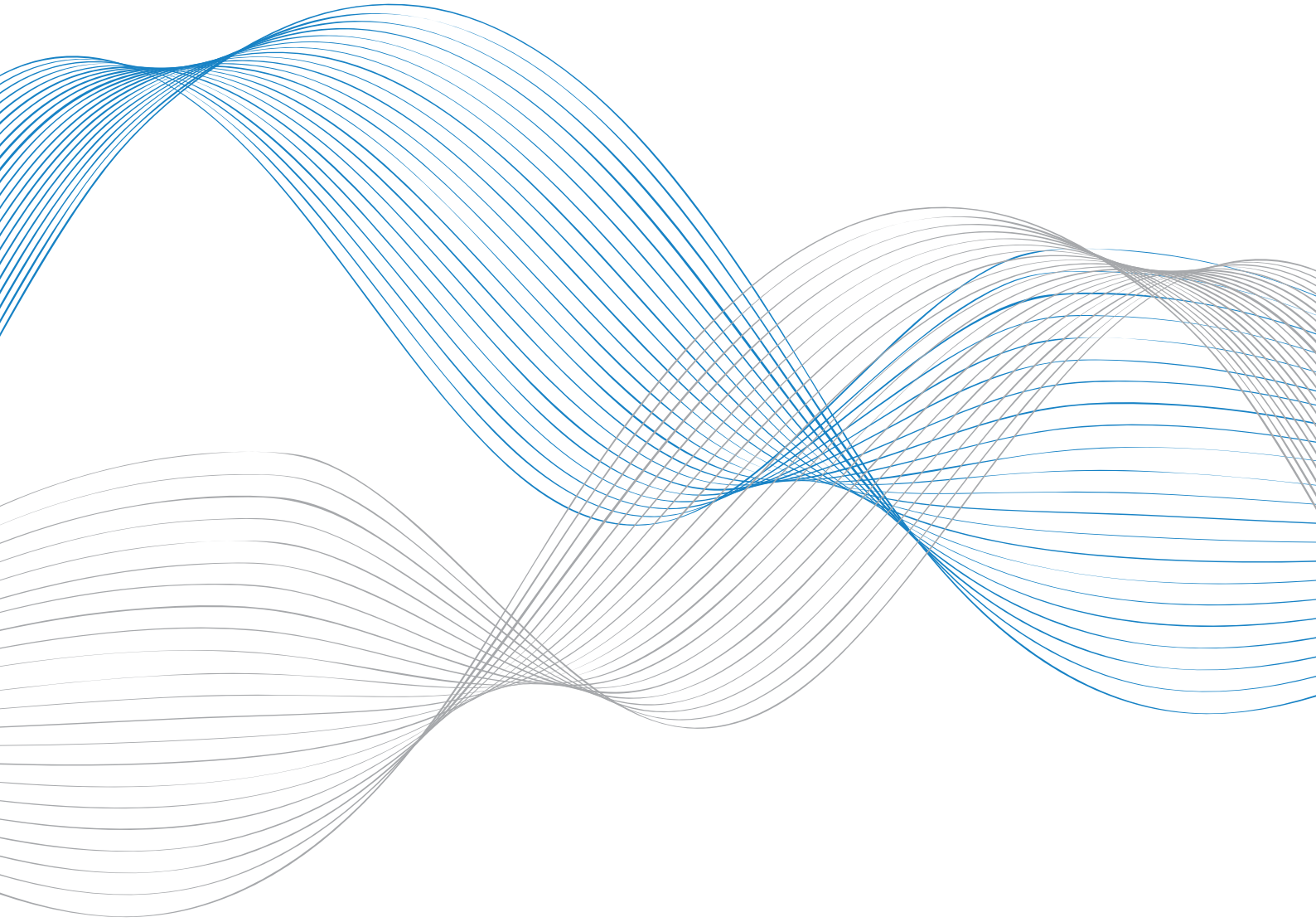
Recce Pharmaceuticals



How synthetic antibiotic development can change the antibiotic treatment model

October 2019

Why we need new classes of antibiotics

Antimicrobial resistance snapshot – Facts and figures

700,000

Each year, 700,000 people die globally due to antimicrobial resistance[3]

19

Between 1980 and 1984, 19 new antimicrobial drugs were approved[6]

10 million

By 2050, it is believed that superbugs will kill up to 10 million people each year (this will supersede deaths projected from cancer)[1]

12

Between 2000 and 2018, only 12 new antimicrobial drugs were approved, most of them additions to existing drug classes[6]

2 million

Every year, 2 million people in the US get an antibiotic-resistant infection, and at least 23,000 people die from it[4]

80-90%

Resistance rates for specific bacterium-antibiotic combinations in certain countries[5]

Introduction

The effectiveness of many antibiotics has declined in recent years due to growing antibiotic resistance[1]. As a result, clinicians have fewer options when treating serious bacterial infections or when treating patients on long-term drug regimes. In these cases, clinicians are frequently reduced to prescribing antibiotics which exhibit a greater level of toxicity to patients, have reduced efficacy and are a greater financial cost than traditional antibiotics[2].

Antimicrobial resistance (AMR) is now one of the world's most urgent medical issues, posing a global threat to public health and garnering increasing attention by government bodies and the World Health Organization[3]. More than 700,000 people die each year globally from infections caused by multidrug-resistant bacteria (superbugs), and millions more suffer with serious infectious complications[4,5]. For these patients, the threat of a 'post-antibiotic era' has already become a reality.

Unless addressed, it is forecast that by 2050 AMR will kill up to 10 million people each year, overtaking deaths projected from cancer, diabetes or car accidents[1]. Furthermore, standard medical procedures such as surgery, organ transplants and cancer treatments will pose a significantly greater risk and may even not be possible.

One of the reasons that AMR is a constantly evolving obstacle is that, as a consequence of bacteria's natural ability to modify its genetic code under the selective pressure of antibiotics, mutations can be introduced into the genes underlying a drug's target[7,8,9]. In addition to this ability to continuously adapt to changing environmental conditions, develop mutations and evolve, bacteria are also capable of acquiring resistance from other bacteria in a process involving gene transfer[10]. This evolutionary pressure has been exacerbated by global overuse of antibiotics in agriculture and animal husbandry as well as over prescribing, especially prominent in outpatient settings such as clinics and emergency departments[11,12].

Almost every antibiotic on the market is based on scientific discoveries from over 30 years ago. As of March 2019, a total of 42 antibiotics (small molecule drugs) were in development to treat serious bacterial infections: 39 were in Phase I-III clinical trials and 3 have been submitted for regulatory approval in the US or Japan. Of these, only a small number are likely to reach the market[13]. The global antibiotic pipeline therefore remains deficient and the drugs most advanced in development do not include any new class of molecules or new mechanisms of action.

Development of new antibiotics has slowed as a result of both scientific barriers and economic challenges. Lower return on

Introduction cont...

investments have historically made this space less attractive to biopharmaceutical companies: since antibiotics are used acutely, rather than chronically, and with good stewardship of existing antibiotics and the prioritisation of their use, antibiotic drugs are only prescribed when really needed as a treatment or prevention[14,15].

National governments and medical bodies, private groups, and the World Health Organization are all working to urgently address the growing threat from AMR and, as a result, there are now a number of initiatives in place that can support R&D costs, provide accelerated regulatory pathways, extend market exclusivity, and remove market barriers. Economic models comprising both 'push' incentives to help companies get started with antibiotic development and 'pull' incentives to get new antibiotics on the market are also being developed.

The need for new antibiotics has never been greater as resistance has developed to most, if not all, currently approved antibiotics, and new types of resistant mechanisms and multidrug-resistant bacteria continue to emerge and spread globally[16,17].

Unlike current antibiotics which have been derived from naturally occurring sources and/or have been modified to give them an additional spectrum of activity, Recce Pharmaceutical's ("Recce") late-stage pre-clinical asset, RECCE® 327, is a synthetic antibiotic with broad spectrum activity and a novel, universal mode of action. It is one of the first truly new classes of antibiotic in over three decades and has been designed specifically to address antibiotic-resistant bacteria (superbugs).

Initially developed for the treatment of blood infections and sepsis derived from *Escherichia coli and Staphylococcus aureus* bacteria, RECCE® 327 has opportunities across several other important indications. Sepsis is a potentially life-threatening condition most commonly caused by bacterial infection in the blood (septicaemia) and results in the immune system mounting a hyperactive inflammatory response to the bacteria/toxins, which can lead to tissue and organ injury, and ultimately death. There are currently no drug therapies available specifically targeted for the treatment of sepsis, and therefore there is a desperate and unmet medical need for new, safe and efficacious treatments.

"RECCE® 327 is a synthetic antibiotic with broad spectrum activity and a novel, universal mode of action."

RECCE® 327 – Broad spectrum antibacterial profile

Recce's novel class of synthetic antibiotics demonstrate rapid, potent and broad spectrum (Gram-positive and Gram-negative) activity, including that against serious and potentially life-threatening multidrug-resistant pathogens.

This new class of antibiotics are bactericidal and therefore kill bacteria rather than inhibiting their growth.

Time-kill assays of RECCE® 327 against standard and superbug bacteria

In Minimum Inhibitory Concentration (MIC) and Minimal Killing/Bactericidal Concentration (MK/BC) testing, RECCE® 327 demonstrated high potency against a range of Gram-positive and Gram-negative bacteria pathogens including *S. aureus, E. coli, Pseudomonas aeruginosa* and their drug-resistant forms. RECCE® 327 exhibited a fast-acting mechanism therefore killing the bacteria at clinically practical rates. Notably, the results showed equal rates against the standard-form bacterial pathogens and their drug-resistant equivalents.

Table 1: Rate of RECCE® 327 killing activity against bacterial pathogens and their drug-resistant forms

Rate RECCE® 327 acts against standard bacteria *in vitro**	
S. aureus	20 - 60 mins
E. coli	20 - 60 mins
P. aeruginosa	1 - 24 hrs
S. pyogenes	20 - 60 mins
C. difficile	20 - 60 mins

Rate RECCE® 327 acts against a number of superbugs *in vitro**	
S. aureus	20 - 60 mins
E. coli	20 - 60 mins
P. aeruginosa	1 - 24 hrs
Same rapid rate for standard bacteria and their superbugs	

*Concentrations of 1,000 ppm were used for all bacteria except *P. aeruginosa*, which used 2,000 ppm.

RECCE® 327 – Broad spectrum antibacterial profile cont...

Evaluation of RECCE® 327 against ESKAPE pathogens and priority bacteria

The scientific community has developed the acronym "ESKAPE" for the six bacterial pathogens most commonly associated with AMR i.e. *Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa,* and *Enterobacter* species. The ESKAPE pathogens are a leading cause of nosocomial infections across the world. Further testing of RECCE® antibiotics demonstrated their potent antibacterial activity against four of these life-threatening pathogens, notably *E. faecalis, S. aureus, K. pneumoniae* and *P. aeruginosa*. However, testing against *A. baumannii* and *Enterobacter* species has so far proved impractical as they are prohibitively regulated.

Furthermore, to help governments, researchers and industry focus their resources on key pathogens associated with antibiotic resistance, in February 2017 the World Health Organization published a priority list of the most globally significant pathogenic bacteria which pose the biggest threat and, as such, signify an urgent need for the development of new treatments. The list included 12 antibiotic-resistant bacteria that were prioritised into three categories: critical, high and medium. Three of the bacteria pathogens listed are ESKAPE pathogens.

RECCE® 327 displayed a positive response against *Enterobacteriaceae*, *Helicobacter pylori, Neisseria gonorrhoeae* and *Streptococcus pneumoniae*, meaning its bactericidal capability has been shown against a total of seven priority list pathogens – including two categorised as critical.

"RECCE® 327 has shown bactericidal capability against a total of seven priority list pathogens."

Table 2: World Health Organization priority pathogens list for R&D of new antibiotics and activity of RECCE® 327

Priority 1: CRITICAL	RECCE® 327
Pseudomonas aeruginosa, carbapenem-resistant	1
Enterobacteriaceae, carbapenem-resistant, ESBL-producing	2
Acinetobacter buamannii, carbapenem-resistant	Not tested
Priority 2: HIGH	
Enterococcus faecium, vancomycin-resistant	3
Staphylococcus aureus, methicillin-resistant, vancomycin-intermediate and resistant	4
Helicobacter pylori, clarithromycin-resistant	5
Neisseria gonorrhoeae, cephalosporin-resistant, fluoroquinolone-resistant	6
Campylobacter spp., fluoroquinolone-resistant	Not tested
Salmonellae, fluoroquinolone-resistant	Not tested
Priority 3: MEDIUM	
Streptococcus pneumoniae, penicillin-non-susceptible	7
Haemophilus influenzae, ampicillin-resistant	Not tested
Shigella spp., fluoroquinolone-resistant	Not tested

1: Active *in vitro* against Recce's own *P. aeruginosa* superbug.
2: Active *in vivo* against a carbapenem-resistant *E. coli.*
3: Active *in vitro* against a very closely related species: *Enterococcus faecalis,* vancomycin-resistant.
4: Active both *in vitro* and *in vivo* against MRSA (methicillin-resistant *Staphylococcus aureus*).
5: Active both *in vitro* and *in vivo* against three strains (two of which are superbugs).
6: Active *in vitro* (superbug not available).
7: Active *in vitro* against related superbug *K. pneumoniae.*

RECCE® 327 – Broad spectrum antibacterial profile cont...

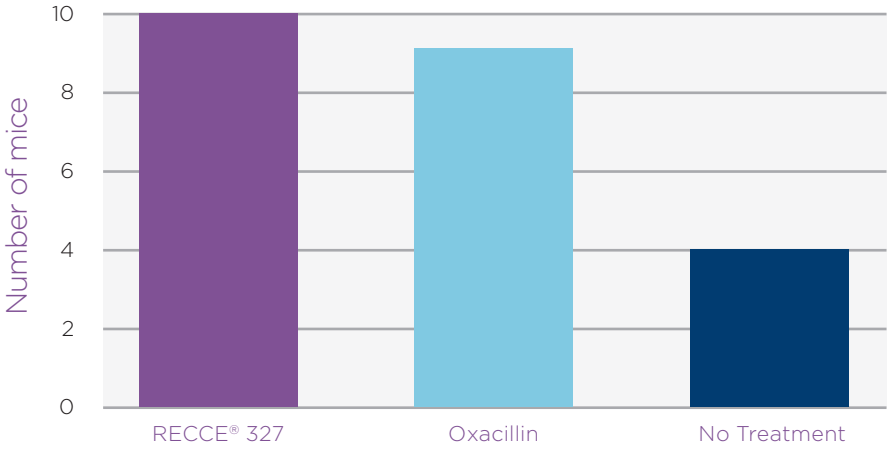
Curative efficacy study

To study the curative efficacy of RECCE® 327 as a treatment for sepsis, Recce's core indication, a sepsis mouse model was created using the drug-resistant form of *S. aureus*, a known primary cause of bacteraemia[18]. The efficacy of RECCE® 327 was examined in a comparison study against Oxacillin, a narrow spectrum antibiotic that is used as a last-resort treatment in the clinical setting (Figure 1).

Three groups of ten mice were each infected with methicillin-resistant *Staphylococcus aureus* (MRSA), an antibiotic-resistant form of *S. aureus*. Over 8 days of infection, one group was administered RECCE® 327 at 132 mg/Kg, while the second group received Oxacillin at 500 mg/Kg, and a third control group received no treatment. All ten mice treated with RECCE® 327 survived, while nine out of the ten mice treated with Oxacillin survived.

By comparison, only four out of the ten mice in the control group survived. Data from this study demonstrates that RECCE® 327 has a similar curative potential to Oxacillin. Since antibiotics are being administered intravenously, they will treat the bacterial infection in the blood as well as any primary site of infection in organ(s). Additionally, since RECCE® 327 is a broad spectrum antibiotic, it would potentially have an advantage in the clinical setting where there is limited time to accurately diagnose the pathogenic bacterial type/strain.

Figure 1: Number of mice that survived sepsis from methicillin-resistant *Staphylococcus aureus* after treatment with RECCE® 327 or Oxacillin



This study was conducted by an independent Contract Research Organisation in the USA.

Preventative efficacy study

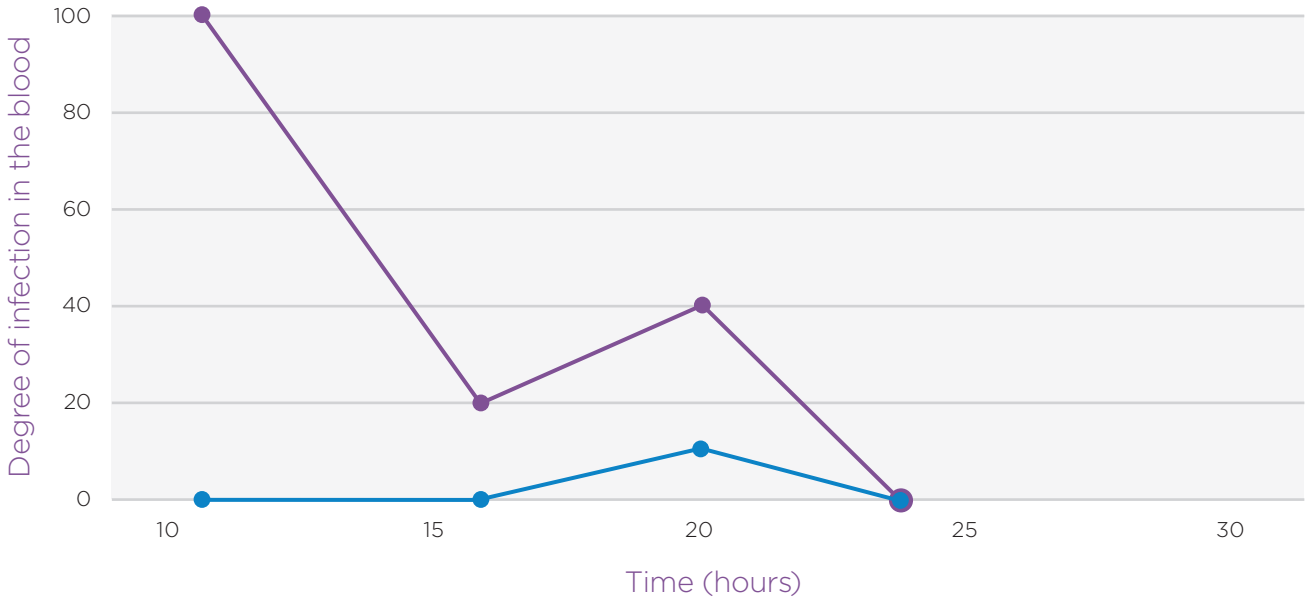
To examine the prophylaxis potential of RECCE® 327, a study was carried out using mice that were infected with *S. pyogenes*, a pathogen that can lead to the development of sepsis (Figure 2).

In one group ten mice were administered a 167 mg/kg dose of RECCE® 327 at 0 hours, whilst the second control group received no antibiotic. Both groups were then immediately inoculated with the same *S. pyogenes* burden into the bloodstream. To allow the bacteria sufficient time to develop and establish an infection in the mice, results were first monitored after 12 hours post-inoculation.

In the group receiving RECCE® 327, no established infection was recorded in the blood. In contrast, in the control group, *S. pyogenes* appeared to clear naturally from the blood after 12 hours, although an infection was present. Further examination of other organs revealed that, in these mice, the bacteria were rapidly colonising the kidneys, which can often lead to catastrophic kidney failure.

In comparison, bacteria in the blood were rapidly killed and unable to establish an infection in the kidneys of mice who received RECCE® 327. This was attributed to the prophylactic/preventative effect of RECCE® 327.

Figure 2: Establishment of *Streptococcus pyogenes* infection in mice with and without RECCE® 327 as a prophylaxis



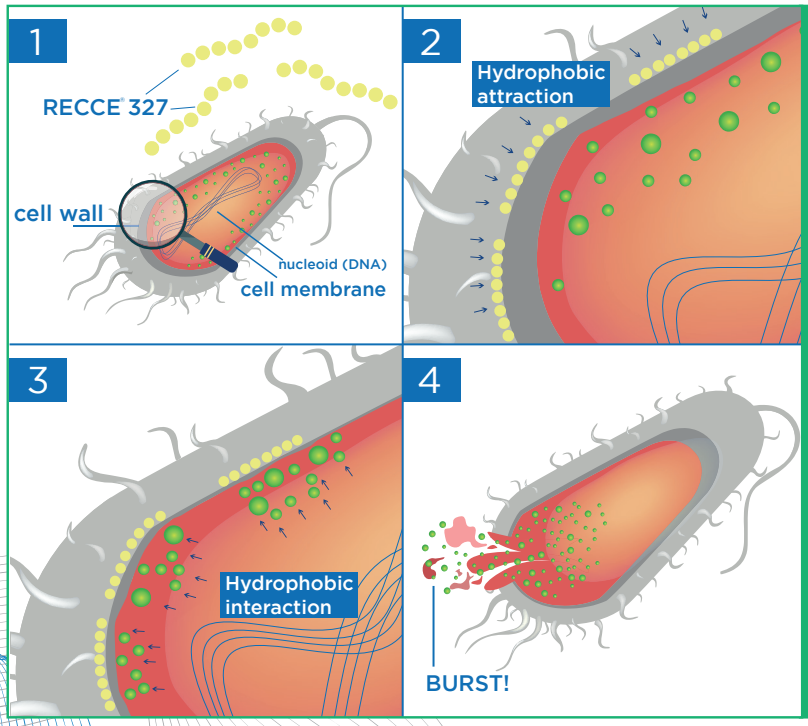
RECCE® 327 – Unique mechanism of action

Unlike current antibiotics, which are typically naturally occurring in certain fungi and soil bacteria, Recce's antibiotics are wholly synthetic and based on a patented polymeric structure; they have been designed to overcome resistance.

Traditional antibiotics inhibit a single target such as bacterial gyrase enzymes, cell wall biosynthetic enzymes, or enzymes required for DNA replication during bacterial cell division. They operate on a 'lock and key' mechanism and therefore only bind to a few active sites on the bacterial target. However, if a mutation is introduced into the target site, then the antibiotic will cease to be effective.

In contrast, RECCE® 327 is non-specifically attracted to the bacteria plasma membrane through hydrophobic interactions, especially to all the proteins of the bacterial plasma membrane. This results in subsequent disruption of the bacterial cell wall, and the natural, unique high metabolic pressure (up to 10 atmospheres) in the bacteria leads to bacterial cell lysis (bursting) (Figure 3). Other non-bacterial cells remain intact as they do not contain high internal pressures.

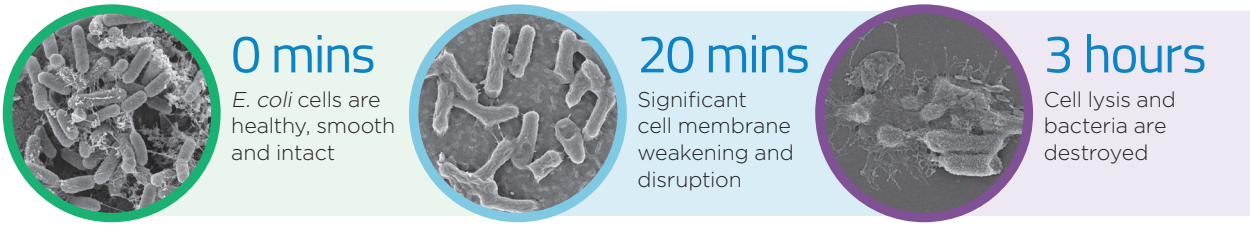
Figure 3: Diagram of RECCE® 327's proposed mechanism of action



This unique mode of action has been demonstrated in an observation study which used RECCE® 327 as a treatment against *Escherichia coli* bacteria.

Microscopic images from this study can be seen in Figure 4.

Figure 4: Electron microscope images of *Escherichia coli* before and after treatment with RECCE® 327



In an *in vitro* study, *E. coli* cells at 10^6 CFU/mL (colony-forming units per millilitre – a measure of viable bacterial cells) were treated with RECCE® 327 at 1,000 ppm and samples then taken at defined time intervals for electron microscopic examination.

The *E. coli* cells were visibly intact and smooth prior to application of RECCE® 327. Following treatment, there was evidence of the cell membrane weakening and the start of disruption at the 20 min mark. By 3 hours, the *E. coli* membrane had lysed (Figure 4).

In another *in vitro* study, which utilized *S. aureus, E. coli* and *P. aeruginosa* cells, no bacterial resistance was seen to emerge with RECCE® 327 even after >25 repeated exposures (Table 3). In contrast, when these bacteria were exposed to a commercial antibiotic, resistance of the bacteria started shortly after repeated exposure.

Recce's novel class of antibiotics show no tendency for the emergence of resistance, even after repeated use. This is believed to be due to Recce's universal mechanism of action and activity against multiple target sites.

Table 3: Summary of antibiotic resistance development after repeated antibiotic use: commercial antibiotic versus RECCE® 327

Bacteria	Commercial antibiotic	RECCE® antibiotic
S. aureus	8 repeats	>25 repeats
E. coli	2 repeats	
P. aeruginosa	6 repeats	

RECCE® 327 – Safety and toxicity studies

The toxicity of RECCE® 327 has been evaluated in non-Good-Laboratory-Practice investigative single intravenous dose studies in mice, rats, rabbits and dogs and in multiple intravenous dose studies in mice, rats and rabbits.

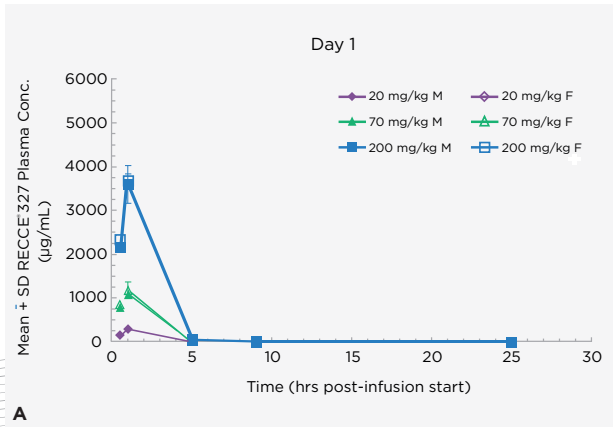
Sprague Dawley rats

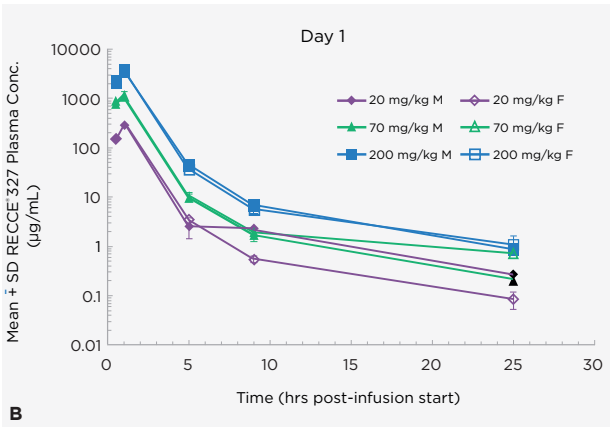
A dose-range-finding and 7-day repeat dose intravenous infusion toxicity study with RECCE® 327 was conducted in Sprague Dawley rats.

The rats were administered a 1-hour intravenous dose of RECCE® 327 at a concentration of either 20 mg/kg, 70 mg/kg or 200 mg/kg, and then blood plasma concentrations of RECCE® 327 were measured at time points 0 (start of infusion), hour 1 (end of infusion), and during the 24 hours following infusion at hours 5, 10 and 25.

As shown in Figure 5A and B, RECCE® 327 was cleared from the blood within hours of the infusion's completion in a dose-dependent manner, with the majority of the antibiotic cleared by 5 hours. These results indicate that the drug concentration in the blood can be well controlled to efficaciously kill pathogenic bacteria without persisting in the plasma long enough to induce toxic effects.

Figure 5: Blood plasma concentrations of RECCE® 327 measured over a 25-hour time period In Sprague Dawley rats. In graph (A) data is shown using an arithmetic scale and in graph (B) a logarithmic scale.





Beagle dog studies

A dose-range-finding intravenous infusion toxicity study with RECCE® 327 was conducted in Beagle dogs.

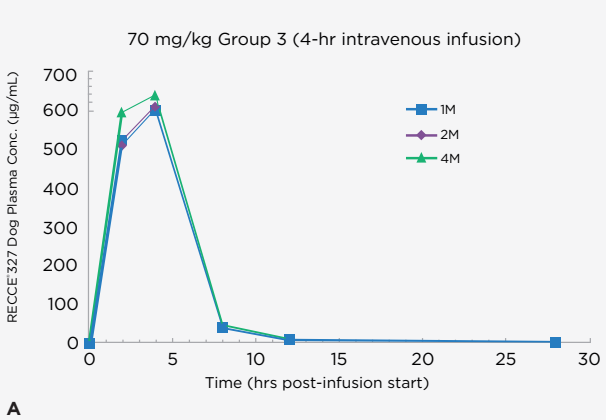
The dogs received a tolerable dose of 70mg/kg, administered intravenously over a 4-hour period. Blood plasma concentrations of RECCE® 327 were measured at time points 0 (start of infusion), hour 4 (end of infusion), and during the 24 hours following infusion at hours 8, 12 and 28.

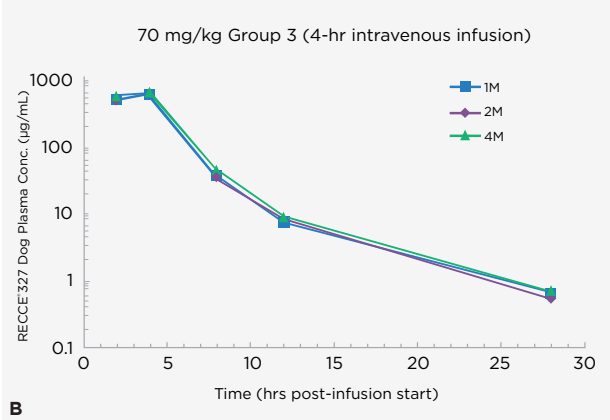
As shown in Figure 6A and B, RECCE® 327 mostly cleared from the blood within a few hours following the 4-hour infusion (Figure 6).

These results further substantiate that RECCE® 327 remains in the bloodstream during infusion for a sufficient time to treat the bacterial infection and then it is subsequently cleared from the bloodstream promptly and toxicity is avoided.

Following this study, the dogs were returned to the colony in good health.

Figure 6: Blood plasma concentrations of RECCE® 327 measured over a 28-hour time period. In graph (A) data is shown using an arithmetic scale and in graph (B) a logarithmic scale.





Testing for genotoxicity and haemolysis

In vitro study

The genotoxicity (propensity to cause mutagenicity/cancer) of RECCE® 327 has been evaluated *in vitro* using non-Good-Laboratory-Practice-compliant Bacterial Reverse Mutation, Mouse Lymphoma Cell Gene Mutation, and Human White Blood Cell Micronucleus assays. The combined results of these studies indicate the genotoxic safety of RECCE® 327 across a wide range of concentrations.

Based on results from haemolysis studies, RECCE® 327 was found to be non-haemolytic in human blood.

RECCE® 327 – Straightforward manufacture and scale-up

An obstacle that many companies face as they shift their focus to commercialisation, especially in the initial testing and trialling phases, is the logistical task of manufacturing and scaling-up a product.

Recce has tackled this early on through the development of a patented, automated and economically attractive manufacturing process for its lead antibiotic candidate: RECCE® 327.

Through investment in a purpose-built, wholly owned manufacturing facility, designed to pharmaceutical specification, the company has built up its in-house manufacturing capabilities to retain complete control of its process. Furthermore, its manufacturing process is reproducible and has a CMC (Chemistry, Manufacturing and Controls) data package, essential for clinical studies.

Recce has demonstrated that its manufacturing process can be scaled-up to generate sufficient product to support Phase I and II clinical trial supply.

Conventional antibiotics are naturally-derived by certain fungi or soil bacteria and therefore rely on timely fermentation processes that require large-scale bacterial culture and then several subsequent purification stages. In contrast, Recce's synthetic process gives rise to a 99.9% product yield in several hours, a considerably efficient process. Furthermore, it requires no specialized or expensive waste removal and presents no risk of environmental contamination.

The multifaceted quality of RECCE antibiotics is such that it can be formulated for intravenous, topical, nasal, oral, and inhaler use. This versatility will be beneficial when developing RECCE® antibiotics for indications other than sepsis.

Figure 7: Vials of RECCE® 327 for intravenous administration

Sepsis – RECCE® 327 is shifting the antibiotic treatment paradigm

The promising potential of RECCE® 327 as a treatment for sepsis was recognised when it received Qualified Infectious Disease Product (QIDP) designation under the Generating Antibiotic Initiatives Now (GAIN) Act from the Food and Drug Administration (FDA) that allows Fast Track review plus 10 years of market exclusivity post-approval. This 'push' incentive is for antibacterial drugs that are designed to treat life-threatening infections and fill an unmet medical need, thereby bringing urgently required medical treatments into the clinic faster.

RECCE® 327 is currently in the final stages of pre-clinical development and Recce is working closely with the US FDA in its pre-Investigational New Drug (pre-IND) application to enable successful commencement of Phase I studies.

Antibiotics, such as RECCE® 327, which have proven positive capabilities against bacteria that cause bacteraemia, have the potential to play a vital role in modern medicine – especially as emergence of antibiotic resistance becomes more persistent.

Typically, if a patient presents themselves to a physician with signs of septicaemia, with every hour left untreated, there is a 6% increase of mortality[19]. Currently, even the best diagnostic tools are limited in informing doctors with enough speed, the specific strain(s) of infecting bacteria that are causing the symptoms.

Since most antibiotics today are narrow spectrum and specific to singular bacterial strains, current practice is to quickly administer a 'cocktail' of antibiotics. This strategy is expensive and has the potential to promote drug resistance, all the while providing no level of certainty of outcome. Furthermore, toxicological effects associated with many last resort antibiotics can also be detrimental to the patient's health.

In contrast, RECCE® 327 has the potential to be advantageous as clinicians would be able to quickly administer the drug, knowing that its broad spectrum capability would enable it to work on Gram-positive, Gram-negative or drug-resistant forms of bacteria, thereby stopping the infection and improving patient outcomes on a significant scale. Due to the increasing reality and burden of antibiotic resistance, the potential medical need that could be met is vast.

Why we urgently need a sepsis treatment

Sepsis snapshot – Facts and figures

Top 10

Leading cause of death in intensive care units and a top 10 cause of mortality worldwide[21]

27 million

Global burden – approx. 27 million people per annum develop sepsis[20]

215,000

In the US, 215,000 deaths from sepsis are recorded every year[23]

750,000

In the US, 750,000+ cases of severe sepsis are recorded every year[22]

2%

Two per cent of hospitalisations are for sepsis but they make up 17 per cent of hospital deaths[22]

Expensive

Sepsis is the single most expensive condition treated in US hospitals[24]

Increasing

Care is improving but the incidence of severe sepsis is increasing rapidly[22]

$20 billion

Sepsis represents a significant pharmaco-economic burden of >US$20 billion in annual hospital costs[25]

Opportunity

High incidence means the potential market for effective treatments is sizeable[22]

Challenging the economics of the antibiotics business model

Recce's approach to treating bacterial infections has the potential to break the current antibiotic business model.

With 'traditional' antibiotics currently available on the market, physicians are working to prescribe fewer antibiotics, through good stewardship, for fear of them becoming ineffective. However, a reduction in prescriptions dispensed equates to fewer sales – an unsustainable economic model upon which to base a business with a reduced return on investment and associated lack of motivation to develop new antibiotics.

Pre-clinical studies have demonstrated that RECCE® 327 is a drug that has no propensity for resistance in bacteria, irrespective of repeated exposures. Therefore, it has the potential to break the current industry 'block' as a physician can prescribe the antibiotic without concern of it increasing the AMR burden.

The market for antibiotics is dynamic, with the potential to support a premium price, and a product such as RECCE® 327 offers a strong proposition in an area of high unmet need. This would enable the financial dynamics to shift such that the Net Present Value for these products would be positively enhanced.

"The market for antibiotics is dynamic, with the potential to support a premium price, and a product such as RECCE® 327 offers a strong proposition in an area of high unmet need."

Summary

Recently launched antibacterial products are based on established mechanisms of action and generally viewed as incremental advances. It is now recognised that novel mechanisms, such as that offered by Recce's antibiotics, are going to be required to significantly tackle the exponential rise in AMR infections.

As a completely new class of synthetic broad spectrum antibiotics, RECCE® 327 has the potential to be game-changing in terms of producing a much needed treatment for sepsis and in altering the economics of the industry's antibiotic business model.

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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE) is pioneering the development and commercialisation of a new class of synthetic antibiotics with broad spectrum activity designed to address the urgent global health problem of antibiotic resistant superbugs. Recce antibiotics are unique; their potency does not diminish even with repeated use, a common failure associated with existing antibiotic use and the resulting emergence of resistant superbugs. Patented lead candidate RECCE® 327, wholly owned, has been developed for the treatment of blood infections and sepsis derived from *E. coli* and *S. aureus* bacteria – including their superbug forms. 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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