RCE Corporate Presentation

Ord Minnett – Healthcare Forum

ASX:RCE | **FSE**:R9Q

October 2023

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About Recce Pharmaceuticals Ltd

- Recce Pharmaceuticals Ltd (ASX: RCE, FSE: R9Q) is developing a new class of Synthetic Anti-Infectives, protected by Composition of Matter Patent
- Australian clinical-stage biotech company, with a United States presence
- **Strong pre-clinical data package** demonstrating **high bactericidal activity** combined with **very good safety** at expected human therapeutic range
- **Qualified Infectious Disease Product designation**
  - 10 years market exclusivity plus fast track approval*
- RECCE® 327 (main product candidate) has been included on **The Pew Charitable Trusts Global New Antibiotics in Development Pipeline** as the world's only synthetic polymer, sepsis drug candidate in development
- Multiple clinical indications and formulations in Phase I and II addressing unmet medical needs

**Awarded by the US FDA in 2017 for R327 bacteraemia (broad-spectrum bacterial sepsis). Time starts only from potential market approval.*

Board and Management Structure

Dr John Prendergast – Chairman

BSc (Hons), MSc (UNSW), PhD (UNSW), CSS (HU)

US-based, current Chairman and Co-founder of Palatin Technologies, Inc. (NYSE: PTN) and Lead Director of Nighthawk Biosciences (NYSE: HHWK). With extensive experience in the international commercialisation of pharmaceutical technologies, **Dr Prendergast has been responsible for the approval of three new drug applications.**

James Graham – Managing Director & Chief Executive Officer

BCom (Entrepreneurship), GAICD

Six years as former Executive Director and extensive experience in marketing, business development and commercialisation of early-stage technologies with global potential. Mr Graham has served on Recce's Board of Directors for six years and has invested in almost every capital raise to date with a focus on expanding Recce's commercial opportunities and clinical initiatives.

Dr Alan Dunton – Chief Medical Advisor & Non-Executive Director

BSc (BioChem) Hons, M.D. (NYU)

US based, Director of Palatin Technologies. Over three decades of senior pharmaceutical experience incl. President and MD of Janssen Research Foundation (Johnson & Johnson). **Dr Dunton has advanced a number of blockbuster antibiotics** through regulatory review and commercialisation at Fortune 500 companies including Roche. **Dr Dunton has been responsible for the approval of approximately 20 New Drug Applications**; an amalgamation of prescription and OTC products.

Michele Dilizia – Executive Director & Chief Scientific Officer

BSc (Med Sci), Grad Dip Bus (Mkting), BA (Journ), GAICD, MASM

Co-inventor and qualified medical scientist with a specialisation in medical microbiology and regulatory affairs. Ms Dilizia successfully co-led the research and development of Recce's suite of anti-infective compounds, resulting in a portfolio of granted patents across the globe, including a Qualified Infectious Disease Product designation with the U.S. FDA.

Dr Justin Ward – Executive Director & Principal Quality Chemist

BSc (Chem), PhD (Chem), M Pharm, MRACI, CChem

A quality control expert who has worked with leading pharmaceutical companies. He previously held a technical role with Pfizer, involving providing data for the regulatory submissions to the FDA and TGA. Dr Ward is bringing Recce's research and development, and manufacturing up to US FDA requirements

Alistair McKeough – Non-Executive Director

Alistair is a qualified lawyer and specialises in complex commercial matters that require careful and strategic planning. Mr McKeough has extensive experience advising ASX-listed companies and their directors and is a member of the University of New South Wales Law Advisory Council.

Company Overview

Recce Pharmaceuticals Ltd is a clinical-stage biotech company with a new class of novel synthetic anti-infectives

Capital Structure – 24th October 2023	
ASX & FSE Code	RCE, R9Q
Share Price	**AUD $0.455**
4 Week Average Volume	270.9k
Shares on Issue	**203 million**
Unlisted Options (Avg $1.54)	13.9 million
Market Capitalisation	**AUD $92.5 million**
Cash at Bank	AUD $8.36 million*
Top 20 Shareholders	**51%**
Debt	Nil

Before 43.5% R&D Rebate submitted - net benefit from anticipated receipt during present quarter

RCE Share Price and Volume Chart – 12 Months

Multiple near-term clinical readouts

***The global antibiotics market was US$38.08 billion** in 2021 **projected to grow to US$45.30 billion** in 2028 at a CAGR of 2.5%*

*Multiple clinical indications and formulations in Phase I and Phase II addressing unmet medical needs: **Sepsis, UTI, Burn Wounds and Diabetic Foot Ulcer Infections***

*Proprietary **first-in-class, broad-spectrum anti-infectives** against bacteria*

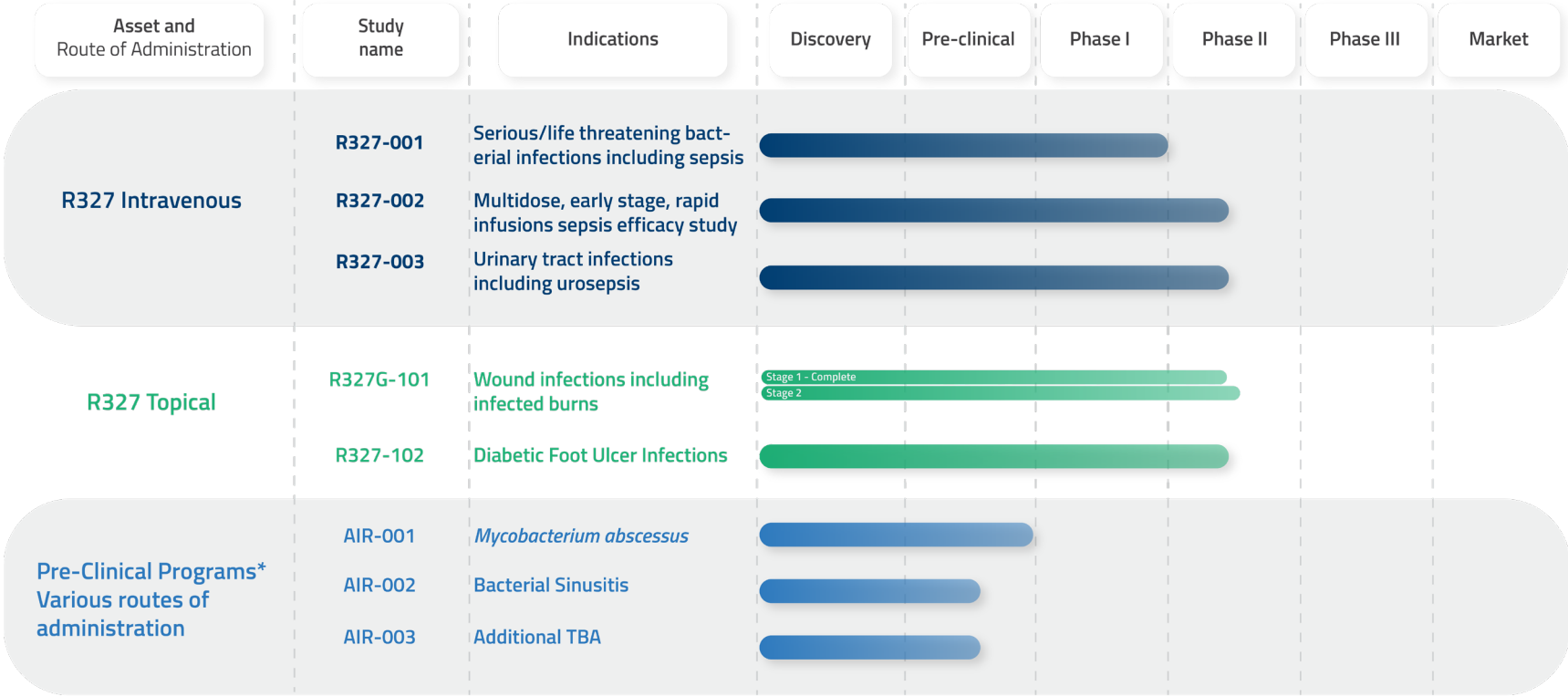
Platform Technology

Recce's products will treat systemic and local infections caused by ESKAPE pathogens, other resistant organisms or when the etiology of the infection is unknown

- Very broad-spectrum coverage of bacteria with **no signs of resistance**
- **Extremely rapid onset of effect** – **measured in minutes** as compared to hours for typical antibiotics
- **Multiple formulations available – intravenous, topical liquid, topical gel and aerosol for inhalation or intranasal**
- **Manufacturing – fast and economical**
- Readily available raw materials
- Prolonged stability of product(s)

Strong Pipeline

Over Various Indications and Upcoming Inflection Points



**AIR – Anti infective Research Unit*

Sepsis – it's a big problem!

48.9 million incident cases of **sepsis** recorded worldwide[1]

11 million sepsis-related deaths recorded[2]

One in three patients who **die** in hospital have sepsis[3]

What is Sepsis?

Sepsis is a life-threatening inflammatory response to infection that has spread in the body.

Economic Impact

Is the **most expensive condition to treat** in the last 8 years[5].

Double the average cost per stay across all other conditions[5].

Social Impact

Kills more people in the US than **prostate**, **breast cancer** and **HIV/AIDS** combined[4].

Currently no drug therapies specifically for the treatment of sepsis[6].

1,2,3 – The Lancet
4 – BioMed Central
5 – University of Texas
6 – International Medicine Journal RACP

Sepsis Patient Journey

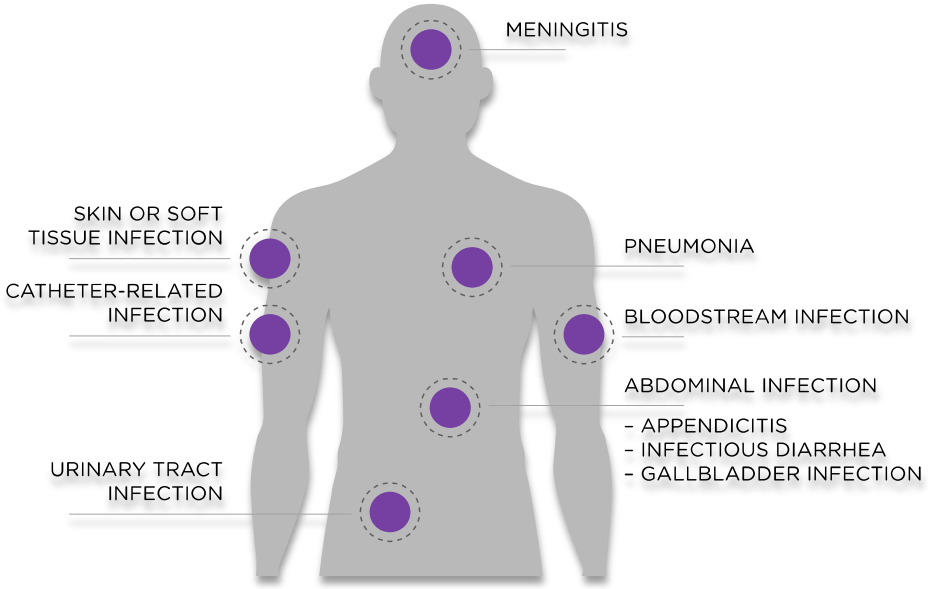
Patient Presents at the Hospital

- 1/3 of patients present non-specific symptoms, leading to delayed treatment and high mortality rate.
- Mortality from sepsis increases by as much as 8% for every hour that treatment is delayed.
- Cost of sepsis care for inpatient admissions and skilled nursing facility: in-patient rehab medical treatment centre admissions was more than USD $62bn/year (USD $170m/day).

Current Treatment Paradigm

- Introducing broad-spectrum antibiotic (s)
- Running antibiograms
- Adjusting antibiotics based on antibiogram results

Early treatment with an effective antibiotic is key to improving patient outcome



Urinary Tract Infections and Urosepsis

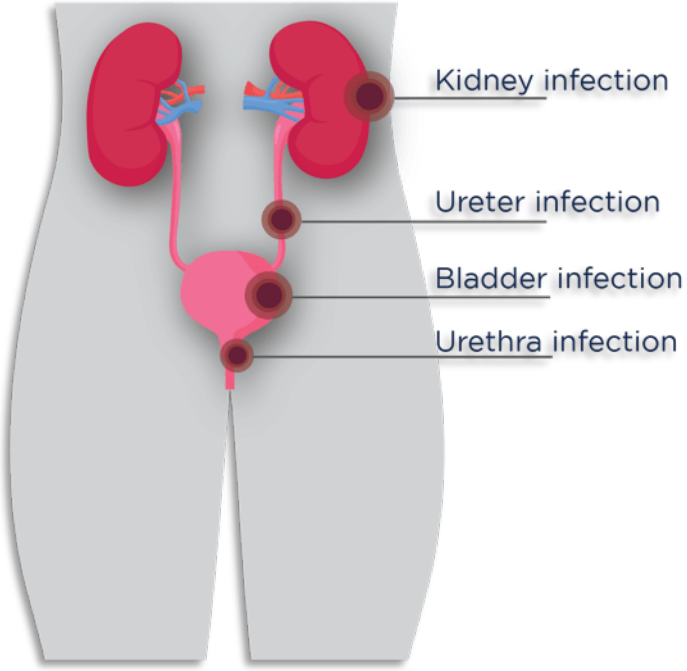
The Infection

- **Urinary tract infection** (UTI) is **one of the most common infectious diseases**
- The most common pathogen causing UTIs is *E. coli* with 90%
- More than 92% of bacteria that cause UTIs are resistant to at least one common antibiotic, and almost 80% are resistant to at least two
- Urosepsis is sepsis caused by infections of the urinary tract, bladder and kidney

Global Burden

- **Globally, more than 404.6 million individuals had UTIs in 2019**
  - Previous years have demonstrated the likelihood of antibiotics killing most UTIs is rapidly dropping

In approximately 30% of all septic patients the infectious focus is localised in the urogenital tract



The Need for a New Class of Antibiotics: Synthetic Anti-Infectives

- **NO** pre-formed natural superbugs.
- Entirely **man-made** and designed with purpose.
- **Universal Mechanism of Action** - does not succumb to resistance.
- **Broad Spectrum capability** and maintains its activity even with repeated use.
- **Empowers clinicians** to confidently and quickly administer an effective antibiotic at first patient presentation.
- On-track to be the only **global clinical stage company** whose drug is shown to be **efficacious** against the full suite of **ESKAPE pathogens.**

Independent Study Undertaken on R327 MoA[1]

By Leading Experts in Bacterial MoA Analysis

- Novel mechanism which targets rapid access to and shut down of bacterial energy production (ATP) which results in bacterial death of both active and resting bacteria.
- **Activity of R327 is measured in minutes** not hours like most other antibiotics.
- Host cells not negatively impacted by RECCE® compounds.

Stage 1

R327 arrests cell growth and permeabilizes cell membranes

Stage 2

R327 disrupts bacterial cellular energetics, depleting ATP

Stage 3

R327 inhibits major bacterial metabolic pathways including protein synthesis and cell division

Stage 4

R327 is rapidly and irreversibly bactericidal

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1 – Dilizia, M., Tsunemoto, H., Quach, D. et al. Elucidating the Mechanism of Action of Novel Polymer-based Synthetic Anti-infective Compound RECCE 327 - Abstract

RECCE® 327 Activity Against *Escherichia coli*

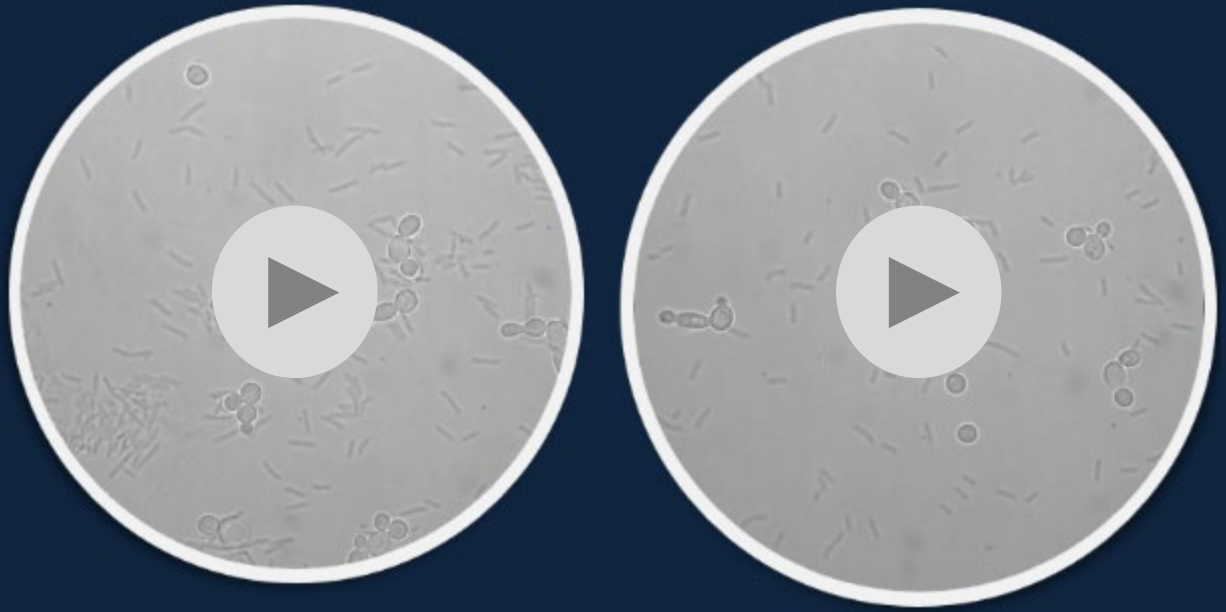
- *E. coli* grows fast. Eukaryotic cells healthy and not affected.

- R327 at 3,000 ppm shown to be highly effective against *E. coli* without affecting growing, healthy eukaryotic cells.

- R327 rapidly and irreversibly shuts down the ATP in *E. coli*, not allowing it to divide and grow.

Without R327

R327 (3,000 ppm)

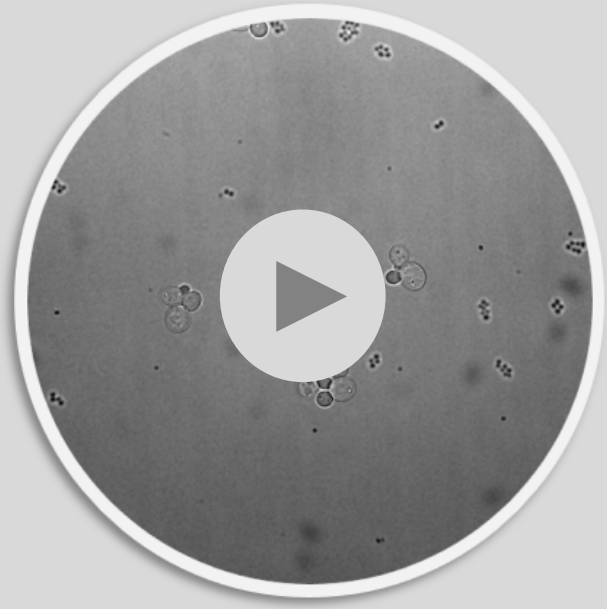


eukaryotic cells ***E. coli***

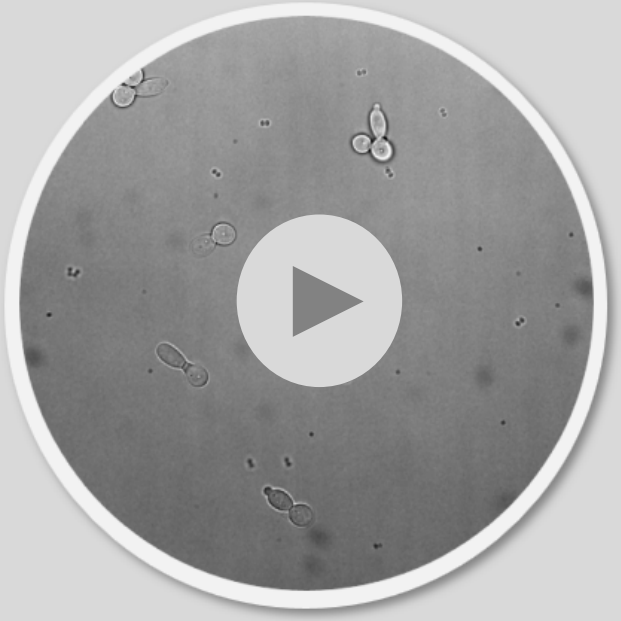
RECCE® 327 Activity Against *Staphylococcus aureus*

- *S. aureus* bacterial growth slower than *E. coli,* not affecting eukaryotic cells.
- **R327 at 2,300 ppm** shows to be highly effective against *S. aureus* without affecting growing, healthy eukaryotic cells.
- **R327 rapidly and irreversibly shuts down the ATP in *S. aureus***, not allowing it to divide and grow.

Without R327

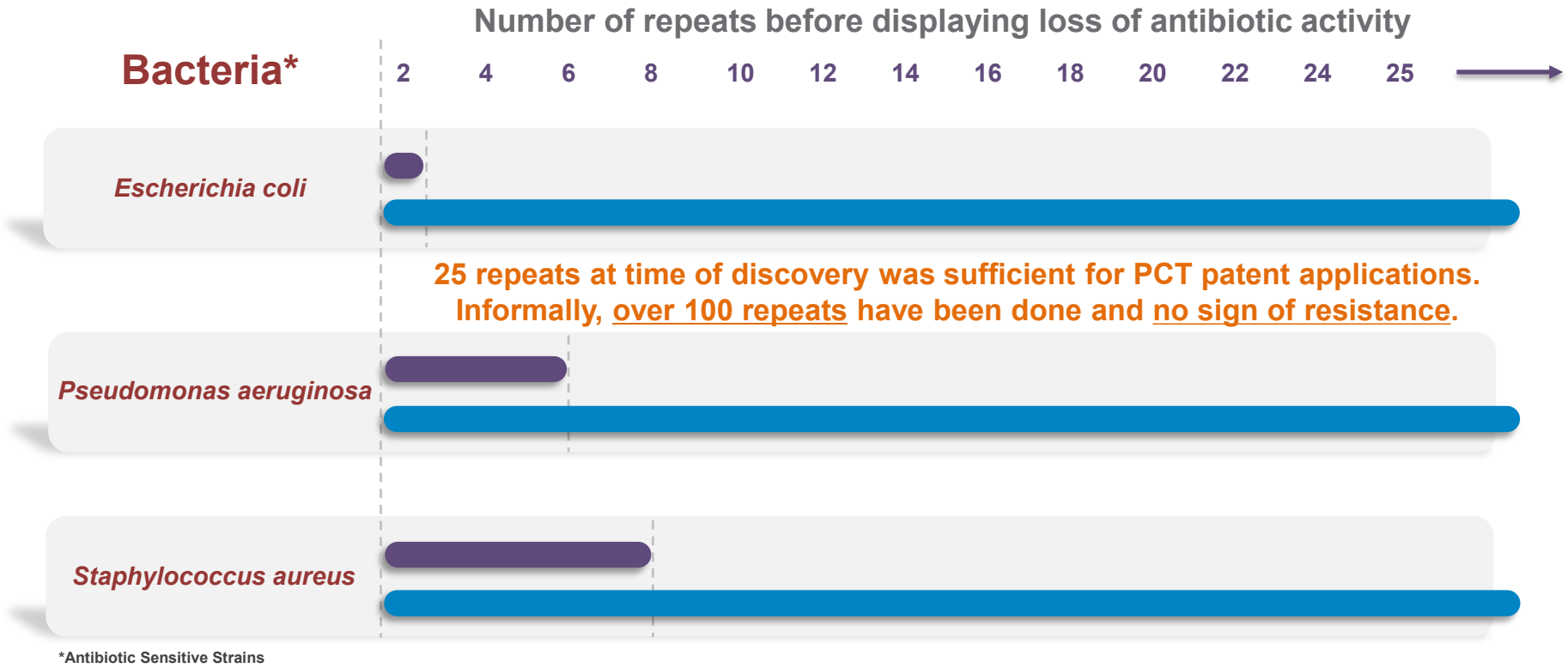


R327 (2,300 ppm)



eukaryotic cells ***S. aureus***

RECCE® 327 Maintains Activity



*Antibiotic Sensitive Strains

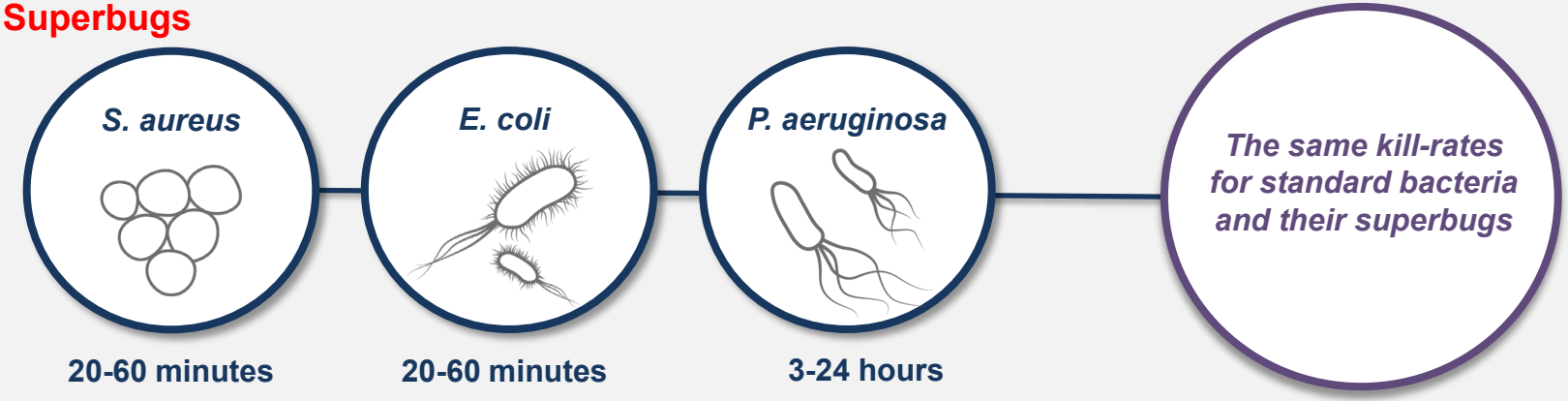
Amoxicillin loses activity after a number of repeats; >25 repeats RECCE® 327 DOES NOT

Amoxicillin RECCE® 327

RECCE® 327 Kills at Practical Speeds

Standard Bacteria

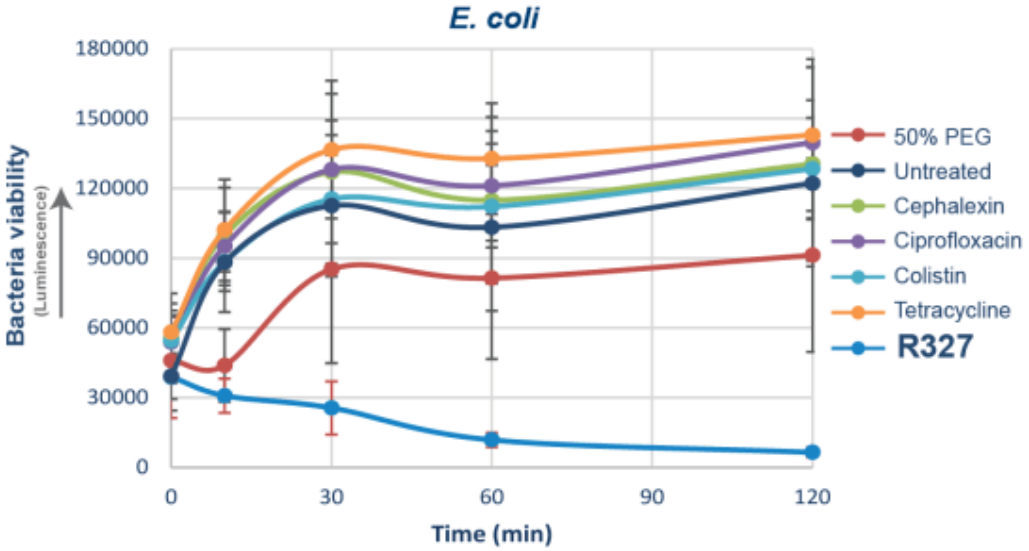
Superbugs



All concentrations of bacteria were 10 cfu/ml
Concentration of R327 was 1,000 ppm against all bacteria

R327 Faster Acting Than Existing Antibiotics

No Prolonged Exposure Needed



- **R327 kills pathogenic bacteria at a faster rate**.
- **R327 designed to work faster** than all existing antibiotics, reinforced by MoA work undertaken by experts in their field.

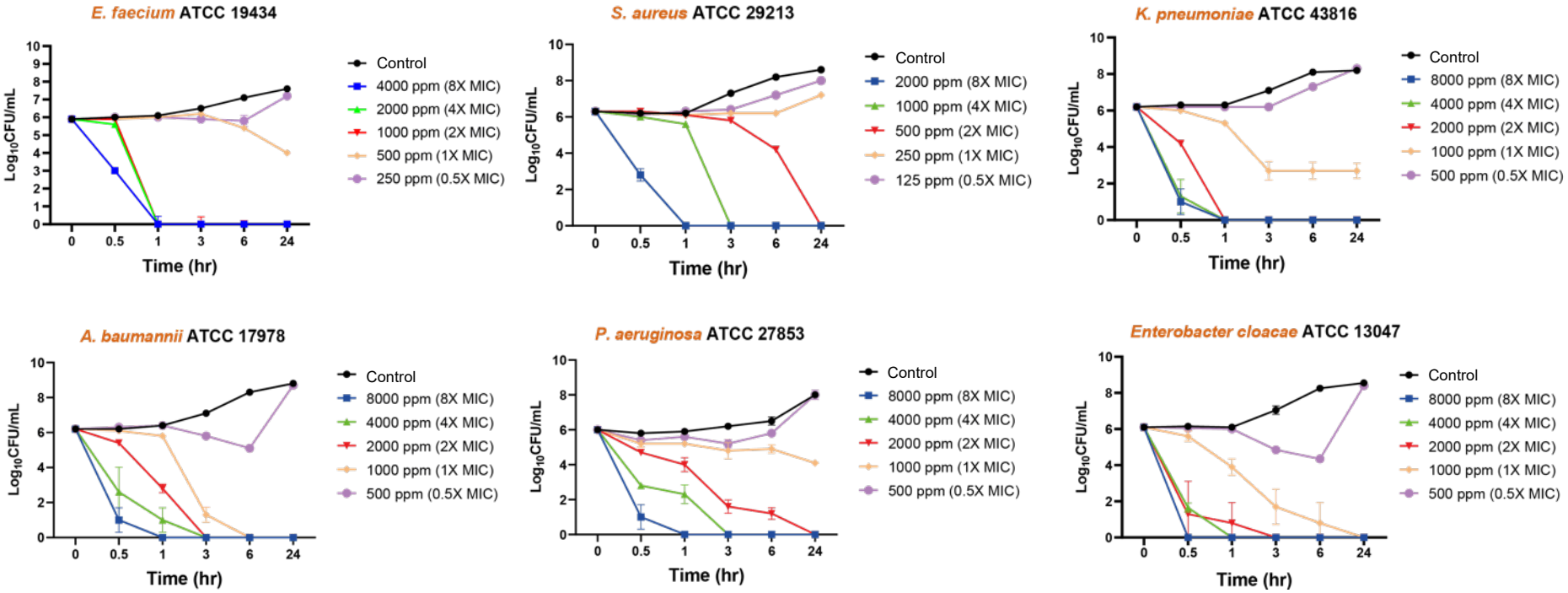
> ***"R327 kills bacteria** in conditions where other antibiotics are ineffective."*
>
> *- Marc Sharp, PhD, Chief Scientific Officer, Linnaeus Bioscience*

R327 is faster-acting against bacteria than other antibiotics – works quickly, without prolonged cellular exposure times required of other antibiotics (extended exposures commonly associated with systemic toxicity).

**Xen14 (a reduction in luminescence correlates with decrease in cell viability)*

**All compounds used at 2X Minimum Inhibitory Concentration (MIC)*

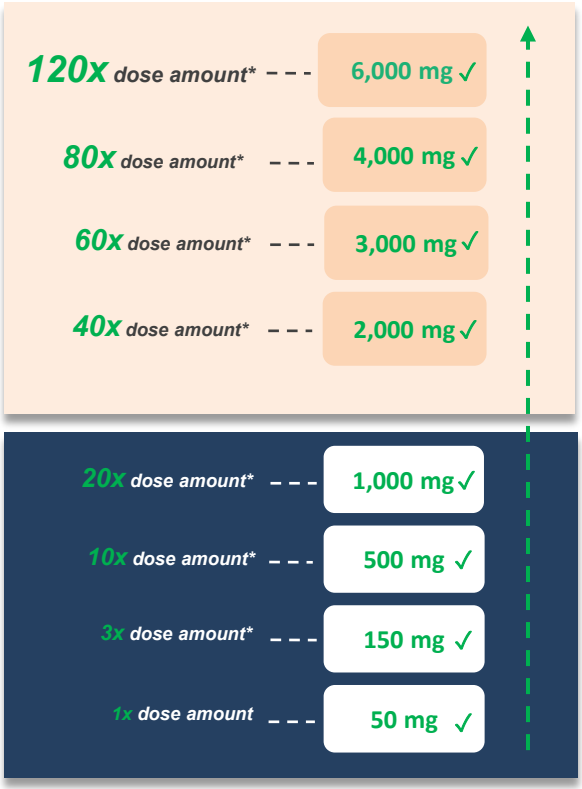
Bactericidal Effect of RECCE® 327 on ESKAPE Pathogens



- ***Average time-kill curves of R327 at various concentrations against strains of ESKAPE pathogens (tested in duplicate)***
- 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, MIC and to measure killing kinetics of treatment with R327 against each strain.

Phase I Human Clinical Trial - Complete

- **Study to assess IV infusion of RECCE® 327 in healthy male subjects as a single ascending dose.**
- Randomized, double-blind, placebo-controlled, safety, tolerability and pharmacokinetics study.
- Single dose of a 1-hour via IV infusion at a uniform rate in hospital setting.
- In concurrence with the Therapeutic Goods Administration clinical trial regulatory procedures, the recruitment for the study is closed and marked '**Complete**' with no '**Serious Adverse Events**' reported.
- **Safe up to and including 6,000mg using a 1-hour infusion**
  - 60 subjects received R327, 20 subjects received placebo
- Plasma concentrations are linear vs. dose and "predictable"



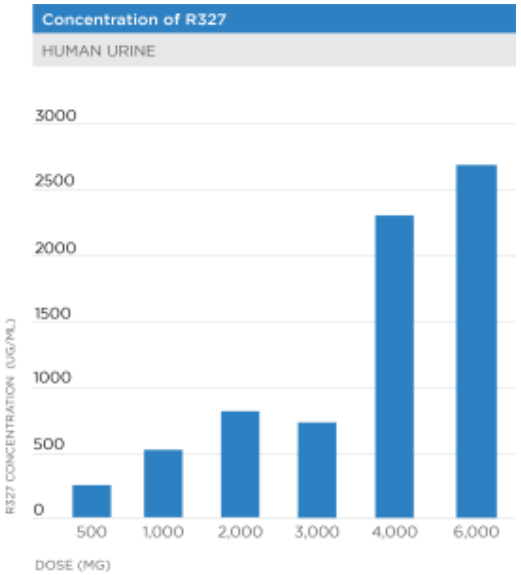
*Dose increase fold based off 50mg

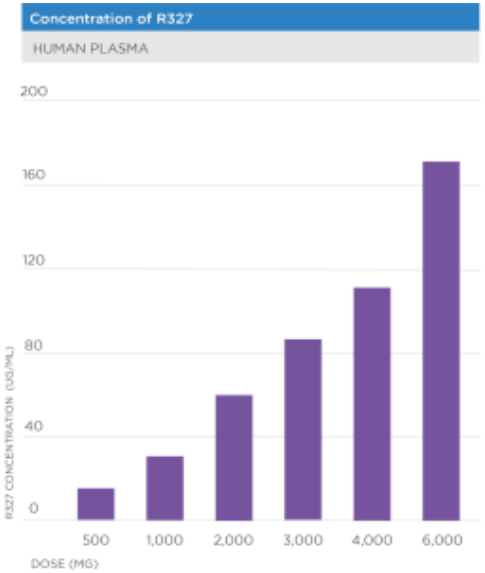
RECCE® 327 - Intravenous formulation – Phase I

Summary of Results – All Primary Endpoints Achieved

- ✓ No serious adverse events (SAEs) or deaths were reported in this study.
- ✓ No clinically significant changes were noted in any hematology parameter(s) in any cohort during the course of the study.
- ✓ No clinically significant changes were noted in any chemistry parameter(s) in any cohort during the course of the study (Kidney and Liver functions all normal – no change in parameters).
- ✓ All coagulation parameters remained within normal limits or were deemed not clinically significant (Normal blood clotting properties were maintained).
- ✓ No clinically significant changes were noted in any urinalysis parameter(s) in any cohort during the course of the study (i.e. no adverse event/side effect).
- ✓ No clinically significant changes were noted in any vital sign (included systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate, and body temperature) parameter(s) in any cohort during the course of the study.
- ✓ No clinically significant changes were noted in any 12-lead ECG parameter(s) in any subject in any cohort during the course of the study (no cardiac event).
- ✓ No clinically significant changes were noted in any cardiac telemetry parameter(s) in any subject in any cohort during the course of the study (no cardiac abnormalities during continuous heart monitoring whilst under observation).

RECCE® 327 Concentrates Safely in the Urine





Concentration of R327 in Urine Compared to Plasma

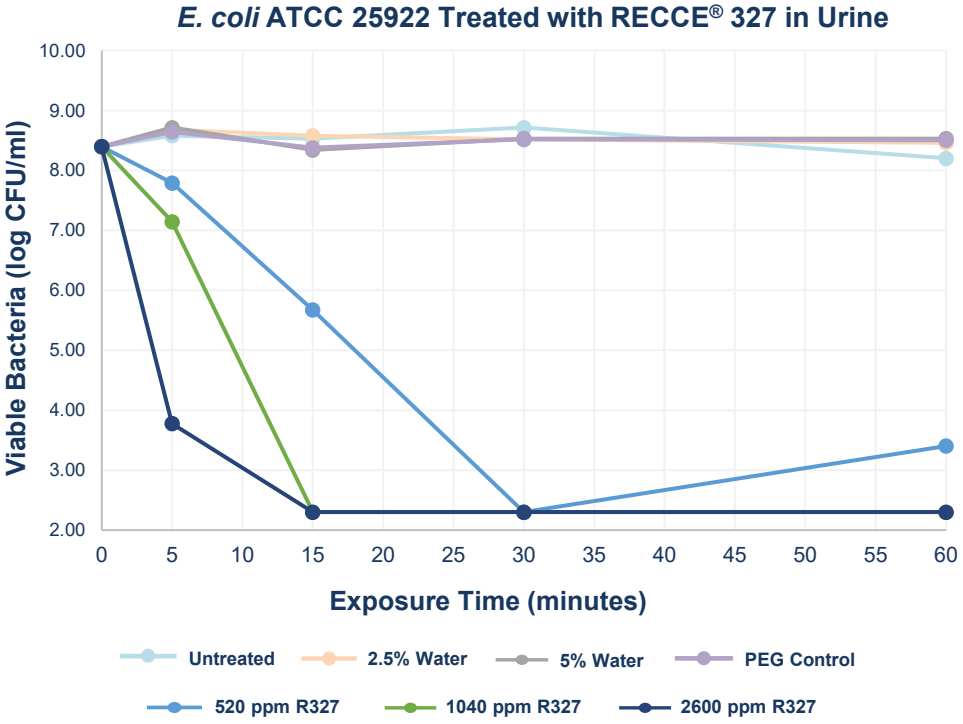
In over 60 healthy subjects

Ratio Urine/Plasma -
16x
17x
14x
9x
21x
16x

- **R327 primary route of elimination** appears to be through the kidney to the ureters and bladder.
- **High concentrations of R327** noted in the urine of Phase I healthy subjects.
- **Insight consistent** with pre-clinical *in-vivo* kidney and UTI bacterial infection studies.

- **Opportunities for therapeutic in array of UTIs (uncomplicated UTI - single dose, complicated UTI, recurrent UTI, treatment resistant etc.)**
- Suggests **broader anti-infective treatment model** in pre-sepsis.

RECCE® 327 Kills Quickly in the Urine



- **R327 in the presence of human urine was able to have a fast (near minutes) effect against *E. coli* and irreversible**
- **Bacteria could not be revived post-treatment**
- R327 capability starting from comparatively low concentrations
- Achieved 6-log reduction in viable cell count

Understanding logs (example of a small colony of 1 million MRSA bacteria)*
A 1-log kill reduces the colony to 100,000 MRSA bacteria after a 90% reduction
A 2-log kill reduces the colony to 10,000 bacteria after a 99% reduction
A 3-log kill reduces the colony to 1,000 bacteria after a 99.9% reduction
A 4-log kill reduces the colony to 100 bacteria after a 99.99% reduction
A 5-log kill reduces the colony to 10 bacteria after a 99.999% reduction
A 6-log kill reduces the colony to 1 MRSA bacterium after a 99.9999% reduction

*https://halosil.com/what-are-logs-and-why-do-they-matter-in-preventing-infections/

Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial

- Assessing R327 at faster administration rates (<1 hour)
- Trial aimed at positioning **R327 as first patient presentation** 'fast-infusion' **designed to stop any bacterial infection** in its tracks in any medical setting
- **Male and female subjects dosed**
- Results from this trial will pave the way for **R327 as a potential first-line treatment for patients suffering from UTI/Urosepsis**
- **Qualified Infectious Disease Product designation**
    - Awarded by the US FDA in 2017 for R327 bacteraemia (broad-spectrum bacterial sepsis).

UTI's are responsible for about 30% of all sepsis infections, defined as 'Urosepsis'

High Dose – 15 minutes

Cohort 4
TBD mg (?)

✓ *Approved to commence*

Cohort 3
3,000mg

Low Dose – 30 minutes

✓ *Safe and well tolerated*

Cohort 2
3,000mg

✓ *Safe and well tolerated*

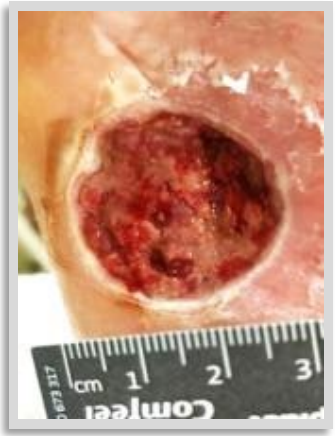
Cohort 1
2,500mg

recce.com.au

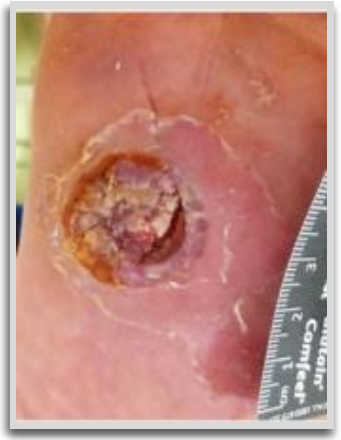
Topical RECCE® 327 – Phase I/II

Patient examples from ongoing Burn Wound trial

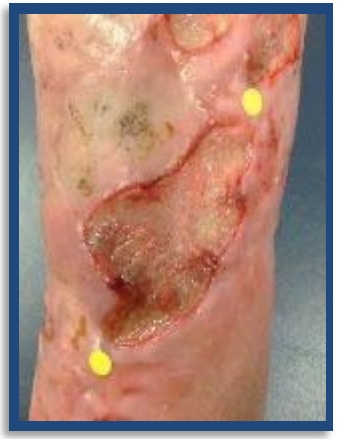
- Patients suffered major burn injury.
- Multiple bacterial species in and surrounding wound.
- Growth swabs with organisms including pathogens from the ESKAPE group of bacteria.
- **Post R327 treatment: healthy skin growth return, reduced swelling and infection, indications of tissue penetration to underlying infection.**
- Building upon the success of these results, the Company has built out its topical treatment programs to include a new Phase I/II clinical study for Diabetic Foot Ulcer infections.



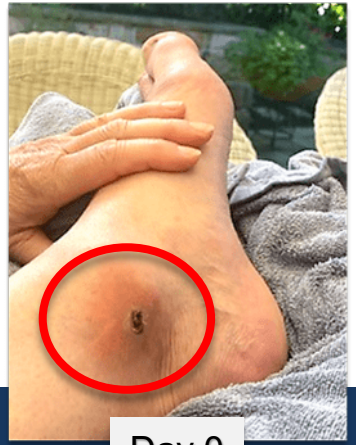
Pre-treatment, significant bacterial infection



Post R327 treatment

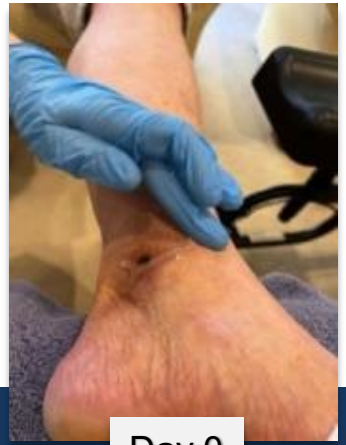


Patient Case Study – TGA Special Access Scheme Category A



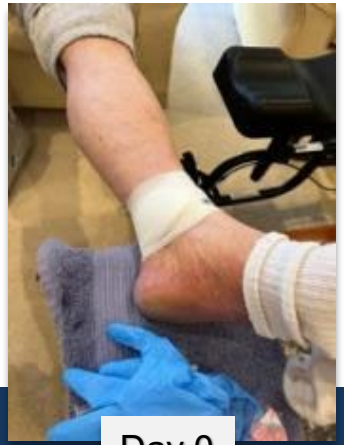
Day 0

Pre-treatment infection



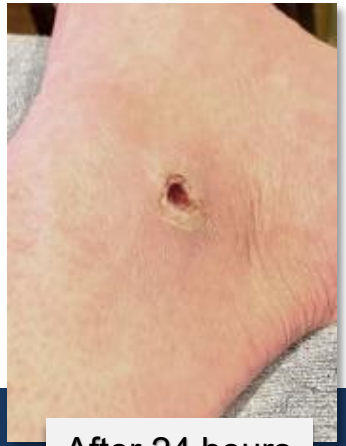
Day 0

First Recce Gel Applied



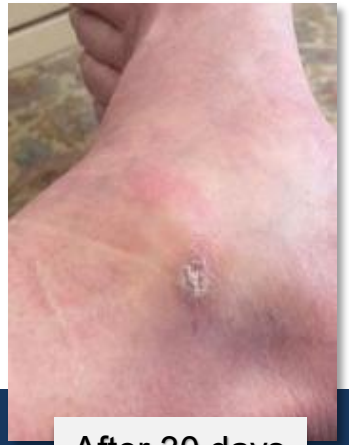
Day 0

Gel Application Complete



After 24 hours

Post Treatment



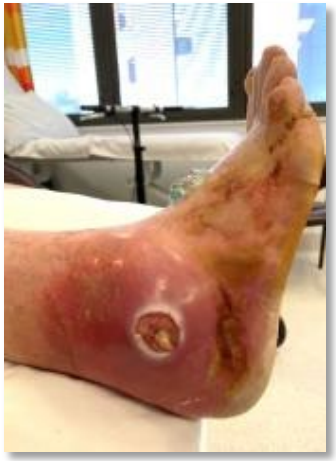
After 30 days

Post Treatment

- Patient Y **unresponsive to 4 x daily Cephalexin for 10 days**
  - Infection spreading and hospital ready.
- With only **one dosing application**, after 24 hours the **infection had clinically responded**
  - Redness and Swelling reduced.
- No pre-treatment wound debridement.
- No stinging at any point reported.
- **R327 Gel worked quickly and effectively**

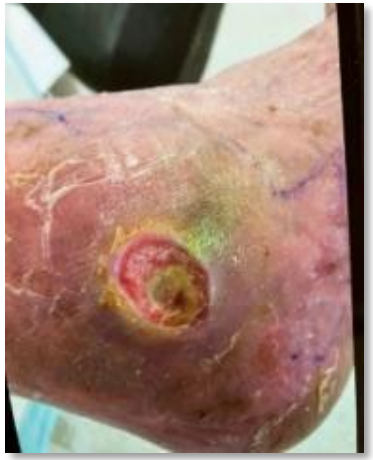
Patient Case Study – TGA Special Access Scheme Category A

Pre-Treatment



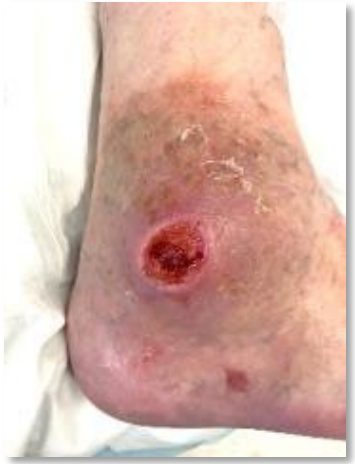
Day 0 – Recce treatment
Significant bacterial infection

Day 7



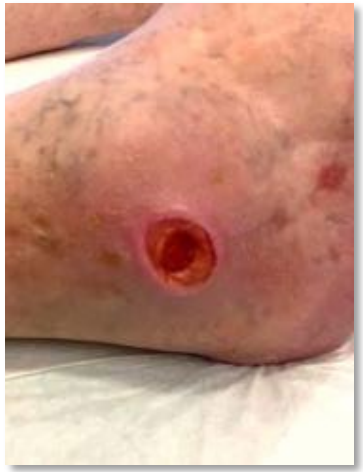
Day 7 – Recce treatment
Initial redness and swelling minimising, wound drying up

Day 10



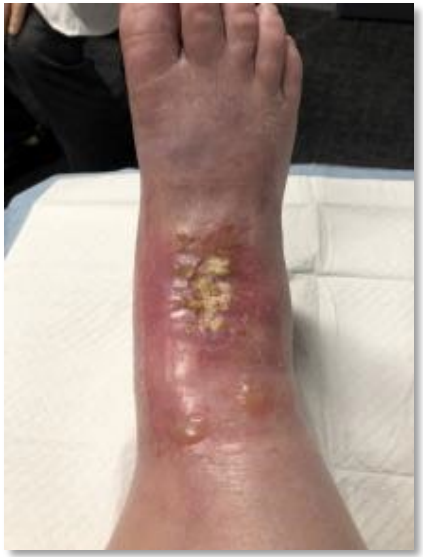
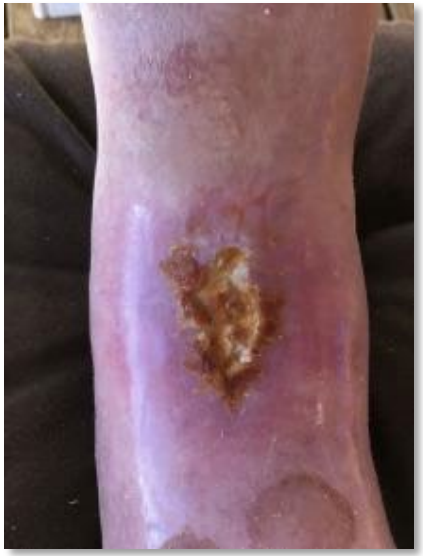
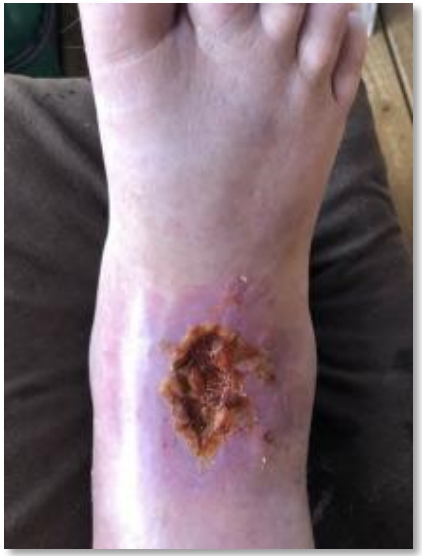
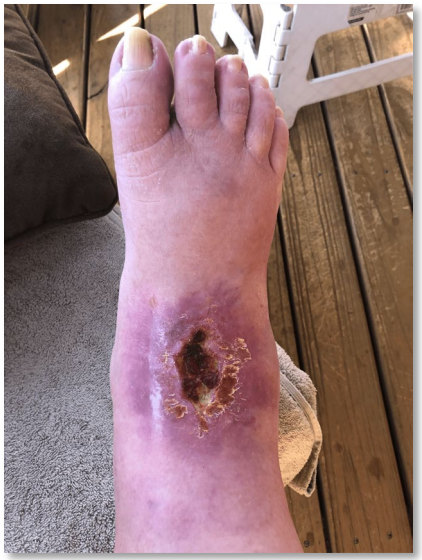
Day 10 – Recce treatment
No signs of infection, no signs of pus formation, wound clearing up

Day 14



Day 14 – Recce treatment
Wound improved, well tolerated

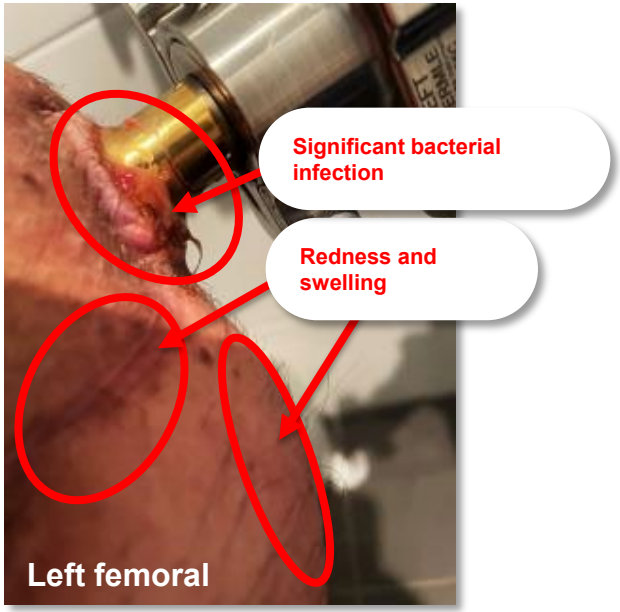
Patient Case Study – TGA Special Access Scheme Category A

Pre-Treatment	Day 7	Day 14	Day 21
			
Day 0 – Pre-treatment wound swab Growing culture of Gram-positive and Gram-negative bacilli	**Day 7 – Recce treatment** Initial redness and swelling of the wound had minimised and found to be drying up.	**Day 14 – Recce treatment** No signs of bacterial growth surrounding the wound	**Day 21 – Recce treatment** Wound had successfully healed, closed and dried up, with no signs of bacterial infection. R327G treatment well tolerated

recce.com.au

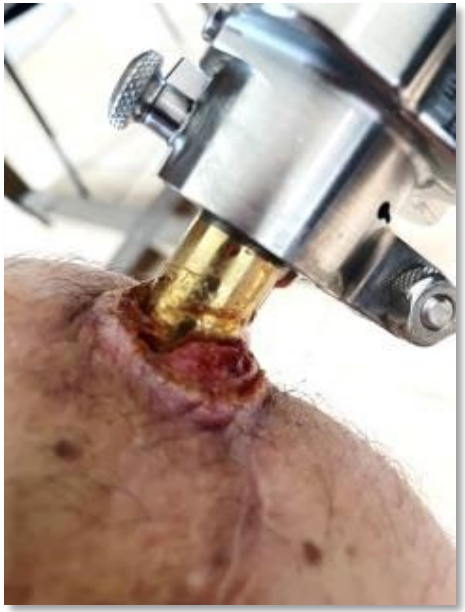
Patient Case Study – TGA Special Access Scheme Category A

Pre-Treatment



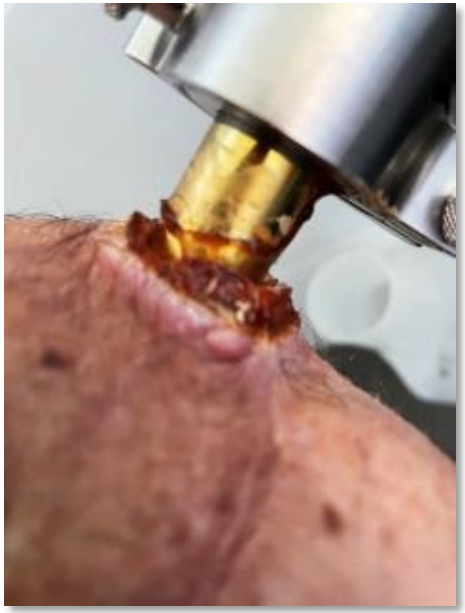
Day 0 – Pre-treatment
Significant bacterial infection, redness and swelling around the implant (upper left thigh)

Day 3



Day 3 – Recce treatment
Initial redness and swelling minimising, wound healing and drying up

Day 7

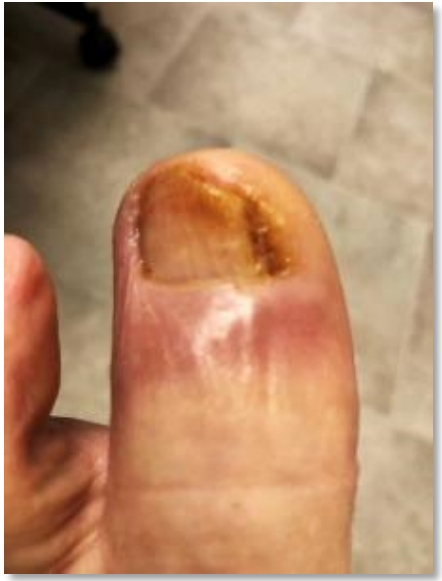


Day 7 – Recce treatment
Wound was dried up and had improved with no signs of redness or swelling. R327G was applied daily and was well-tolerated.

recce.com.au

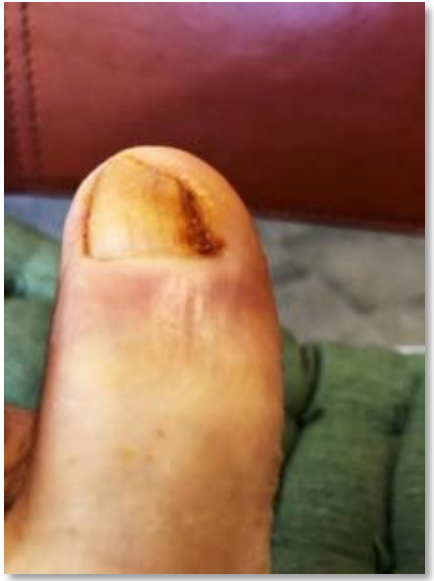
Patient Case Study – TGA Special Access Scheme Category A

Pre-Treatment



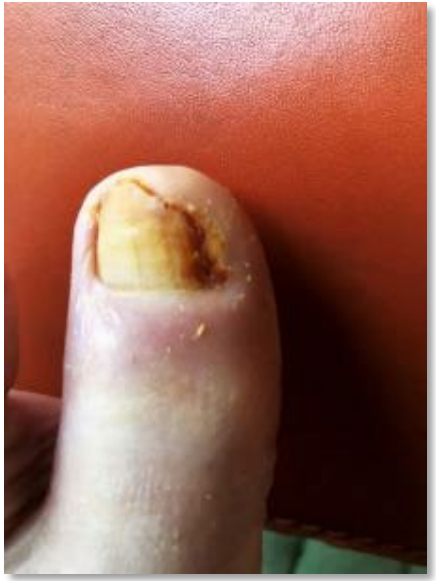
Day 1 – Pre-treatment
Osteomyelitis (serious infection of the bone), signs of initial biofilm formation, not responding to antibiotics

Day 3



Day 3 – Recce treatment
Wound drying up with infection clearing, toe responding to R327G treatment

Day 7



Day 7 – Recce treatment
Wound completely dried up, no signs of biofilm surrounding toenail, swelling significantly reduced

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Phase I/II Diabetic Foot Ulcer (DFU) Clinical Trial

Clinical Trial Overview

- **Human Research Ethics approval received**
- Phase I/II to assess safety and efficacy of R327 on mild skin and soft tissue diabetic foot infections.
- Clinical trial to start at **South West Sydney Limb Preservation and Wound Research Unit,** located at the **Ingham Institute of Medical Research**.
- Unit selected for its **innovative** and **ground-breaking focus** on wounds of the limbs and limb loss, an **under-researched area** in Australian healthcare.

Outpatient Nurses Appointed

- Patients enrolled in Phase I/II now supported by in-home (out-patient) **nurses trained in R327 treatment protocols**
- Appointment of leading out-patient nursing group sees **broadening of DFU patient trial population** – increased probability of dosing completion
- Study across South Western Sydney health district – one of the **highest prevalence rates of diabetes in NSW**
- **Largest DFU study underway in Australia at this time**

Robust Worldwide Intellectual Property Portfolio

Recce's patent portfolio contains over 40 patents and patent applications in the world's major markets.

Filed	Patent Family 1	Expiry	Patent Family 2	Expiry	Patent Family 3	Expiry	Patent Family 4	Expiry
Australia	✓	2028	✓	2037	✓	2037	✓	2041
USA	✓	2029	✓	2037	✓	2037	Pending	-
Europe	✓	2028	✓	2037	✓	2037	Pending	-
Germany	✓	2028	✓	2037	✓	2037	-	-
Spain	✓	2028	✓	2037	✓	2037	-	-
France	✓	2029	✓	2037	✓	2037	-	-
UK	✓	2028	✓	2037	✓	2037	-	-
Italy	✓	2028	✓	2037	✓	2037	-	-
Sweden	✓	2028	✓	2037	✓	2037	-	-
Japan	✓	2028	✓	2037	✓	2037	Pending	-
China	✓	2028	Pending	2037	✓	2037	Pending	-
HK	Pending	2028	Pending	2037	✓	2037	Pending	-
Israel	-	-	-	-	-	-	Allowed	2041
Canada	-	-	-	-	-	-	Allowed	2041

Family 1 group relates to the Company's Unique and Highly Economical Manufacturing Process and use of the Polymer in Treatment of Diseases.

Family 2 relates to the Method of Manufacture, Administration and Application to Treat a Broad Range of Common Human Infections.

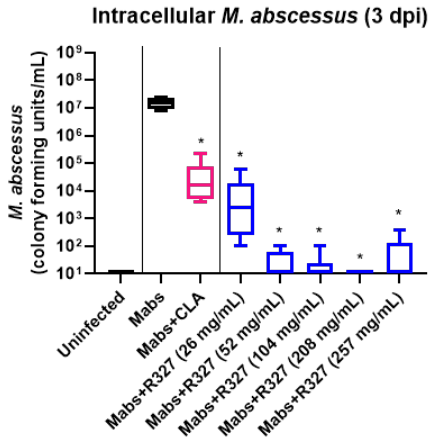
Family 3 relates to a Method of Treatment of a Broad Range of Viral Infections, particularly Parenteral Viral Infection.

Family 4 relates to Process for Preparation of Biologically Active Copolymer, other Patent Cooperation Treaty countries pending/allowed)

RECCE® 327 Activity Against Multiple Bacterial Infections

- **Recce's new Anti-Infective Research (AIR) Unit**
  - Located within Murdoch Children's Research Institute, one of the **top three children's research institutes worldwide**
  - Ongoing pre-clinical programs, **exploring new research development opportunities**

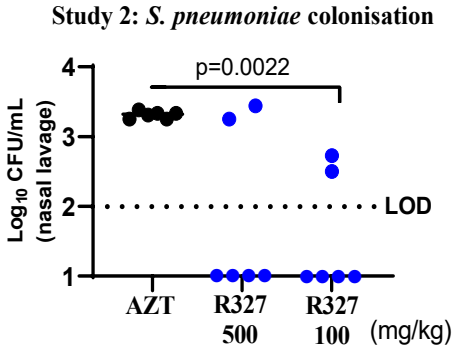
Mycobacterium abscessus Data



Human stem cell-derived macrophages (SCDM) infected with ***M. abscessus*** (Mabs) were treated with R327 or clarithromycin (CLA):

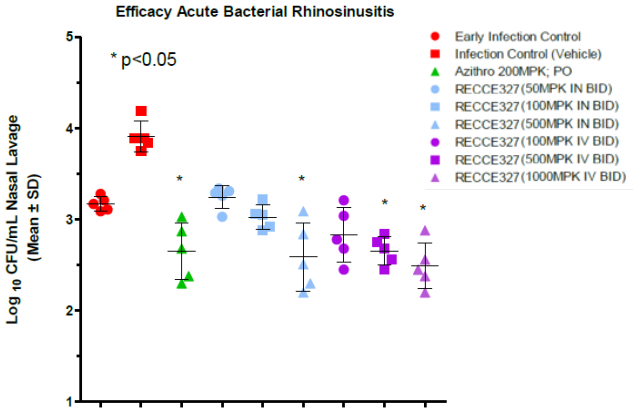
- **R327 demonstrated very good activity against** intracellular ***M. abscessus*** within human macrophages
- **No toxicity** against human SCDM was detected

Bacterial Sinusitis Data



Mice infected with ***S. pneumoniae*** (clinical isolate ATCC 49619) were treated nasally, twice daily for 5 days, with R327:

- **Treatment of non-anaesthetised mice with R327 significantly reduced nasal infection** by ***S. pneumoniae*** compared to azithromycin control.
- **Eradicated infection in 8 out of 12 treated mice**



Nasal cavities of mice infected with ***S. pneumoniae*** (clinical isolate ATCC 49619)

- **Treatment of anaesthetised mice with R327** by both intranasal and intravenous routes **significantly reduced nasal infection by *S. pneumoniae***

Separate study conducted by independent CRO

Manufacturing & Scalability

Manufacturing facility in Sydney's Macquarie Park

- Raw **materials plentiful and cheap** – few $/Kg
- **No expensive waste** – 99.9% product yield
- Automated **manufacture process taking approx. 1 hour, 500 doses** produced per automated run
- This in-house pilot facility provides **clear benefits in cost and scalability** that will be instrumental to meet clinical testing demands as the technology pipeline continues towards commercialisation.
- Demonstrated **capability to support present and future human clinical trials**.

Large strategics are also paying attention

Case studies: Partnering antibiotic assets creates value

US$66 million upfront and Up to US$525 million in potential milestones plus royalties

Exclusive licence agreement for tebipenem HBr

SPERO THERAPEUTICS

September 2022

GSK and Spero Therapeutics announce exclusive licence agreement for late-stage antibiotic that may treat complicated UTIs

Spero will start a new Phase III clinical trial in 2023, following encouraging US FDA regulatory feedback on the proposed clinical trial design

First oral carbapenem antibiotic to potentially treat complicated **urinary tract infections** (cUTI), including pyelonephritis, caused by certain bacteria

Large strategics are also paying attention

Case studies: Partnering antibiotic assets creates value

USD $462 million transaction

novo nordisk®

Paratek's lead product, Nuzyra (omadacycline), is currently available in the US for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI).

PARATEK™

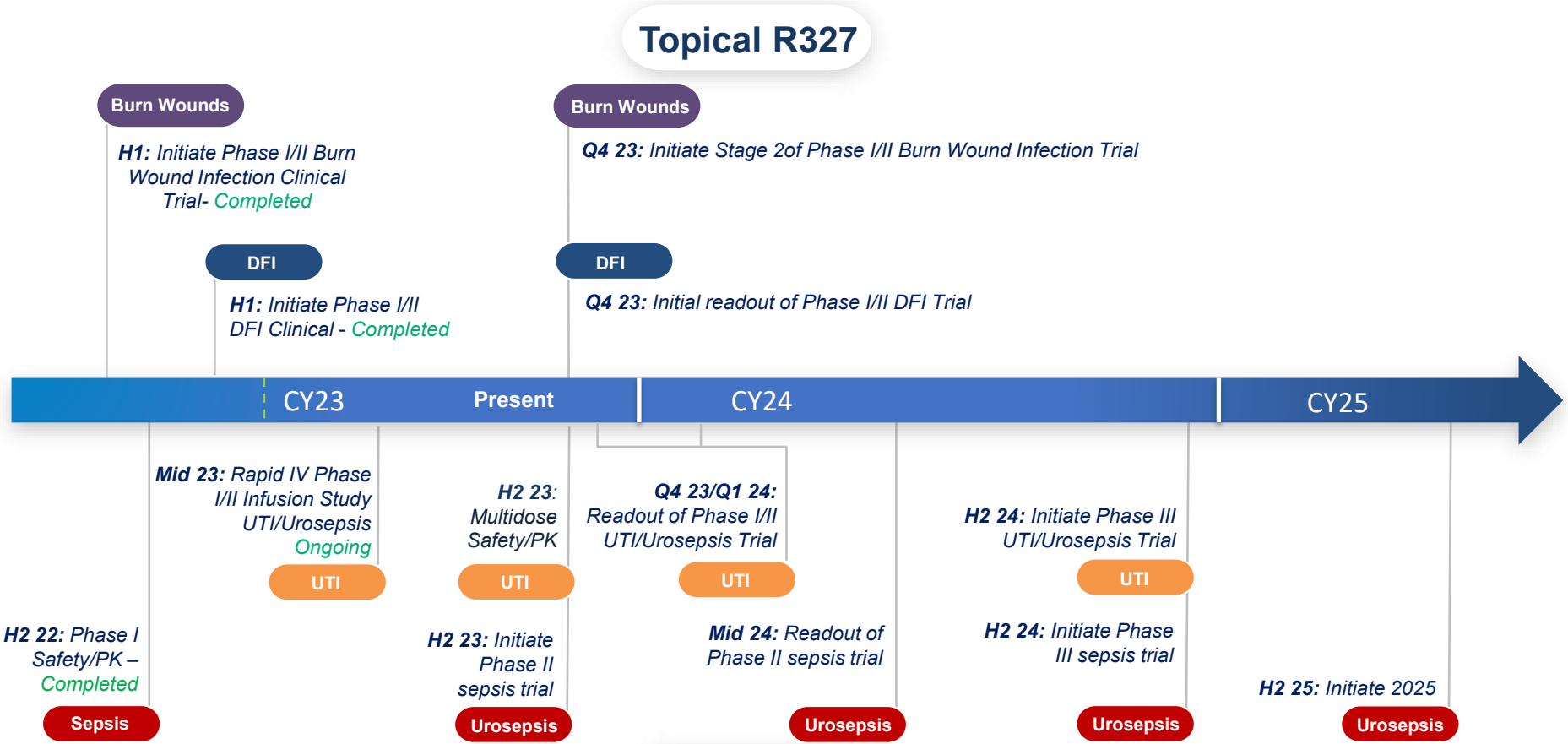
June 2023

The acquisition of Paratek Pharmaceuticals, is Novo Holdings' largest individual investment in AMR therapies to date

Novo Nordisk Foundation, acquired all outstanding shares of Paratek for USD $2.15 per share in cash, plus a CVR of USD $0.85 per share payable upon the achievement of USD $320 million in U.S. NUZYRA net sales in any calendar year ending on or prior to December 31, 2026.

At the time of Nuzyra's approval, Leerink analysts pegged the drug's peak sales opportunity at more than $500 million

Multiple Upcoming Clinical Milestones



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Displayed as calendar years
Milestones are indicative only

Thank you

James Graham
Managing Director and Chief Executive Officer
Recce Pharmaceuticals Ltd
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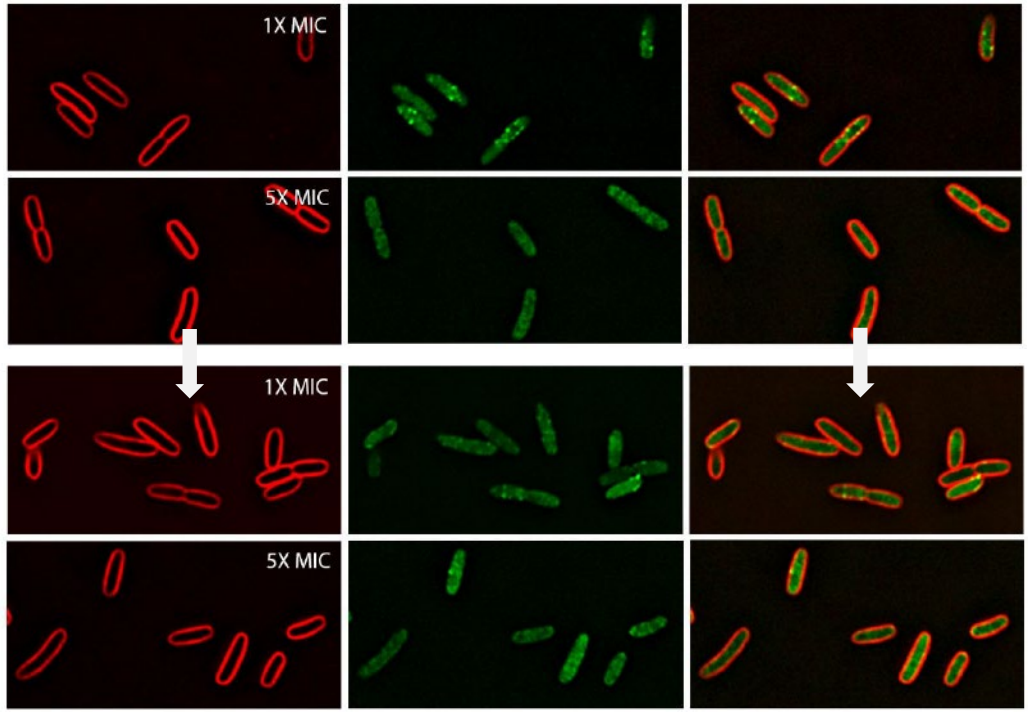
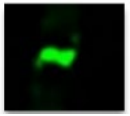
Appendix

RECCE® 327 Mechanism of Action in Practice

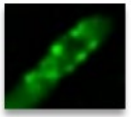
Treatment of R327 on E. coli at 1x and 5x MIC leading to disassembly of the FtsZ-GFP rings



After 30 mins of treatment



***FtsZ rings** – a protein essential for cell division (bacteria reproduction)*



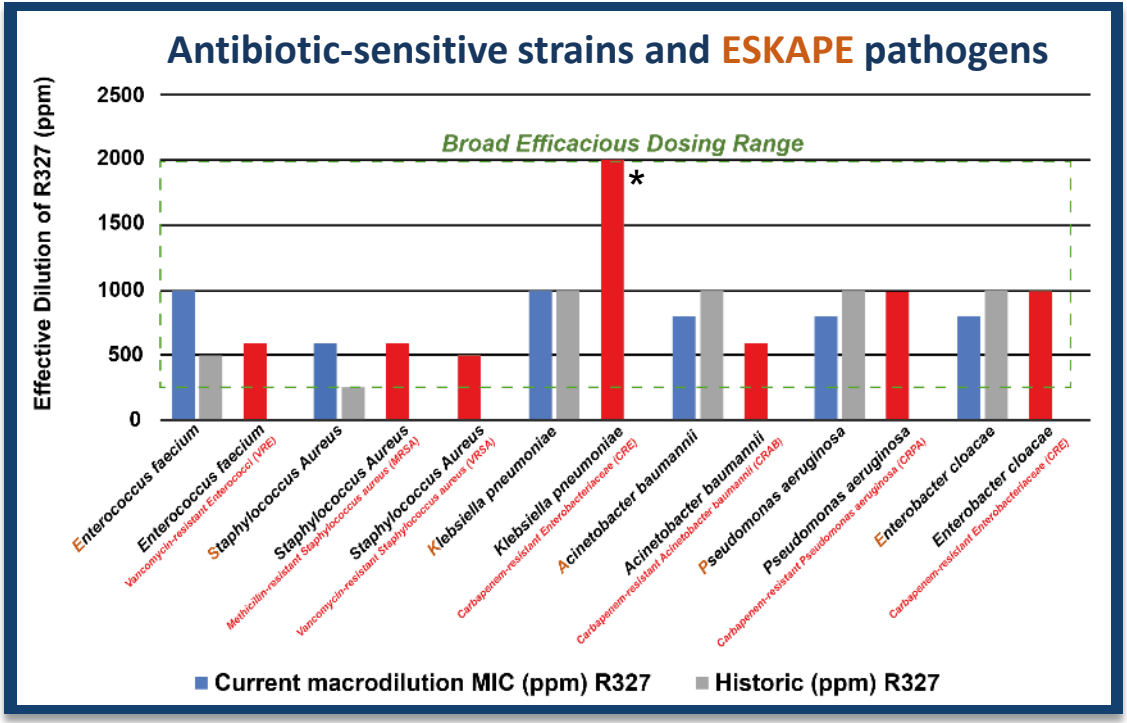
***Disassembled FtsZ rings** – indicating the loss of ability for bacteria to reproduce*

After 60 mins of treatment

Mechanism of Action Studies; Source: Linnaeus Biosciences Inc. San Diego.

ESKAPE Pathogens Can't Escape RECCE® 327

- Bactericidal activity of R327 demonstrated a **three-log** or **99.9% reduction** against all **ESKAPE** strains over 24 hrs at various concentrations and times.
- **R327 remains effective against hypermutated ESKAPE superbugs, including multi drug-resistant (MDR) forms.**
- On track to be the only, global clinical stage company whose drug is shown to be efficacious against the full suite of **ESKAPE** pathogens globally.



Broad spectrum antibiotic efficacy – drug-resistant ESKAPE pathogens especially susceptible to R327 in comparison to standardised bacterial forms

***Data anomaly – since clarified as well within normal efficacious dosing range**

Mechanism of Action – RECCE® 327

- The activity of **RECCE® 327** (R327) was investigated against a wide array of **Gram-positive**, **Gram-negative**, and **mycobacterial species**
  - Including the **ESKAPE pathogens**, ***Bacillus subtilis*** and ***Escherichia coli*** biofilms to determine the effects of R327 on these bacterial species
- Graphs convey ATP levels and viable cells for different bacterial strains treated with 0, 1X, 2X and 5X the MIC (varying PPM's) of R327 for one hour in 10% LB
  - By testing it in 10% LB we were able to **treat all of the strains at the same relative concentrations**

"A unique mode of action that we've not seen before"

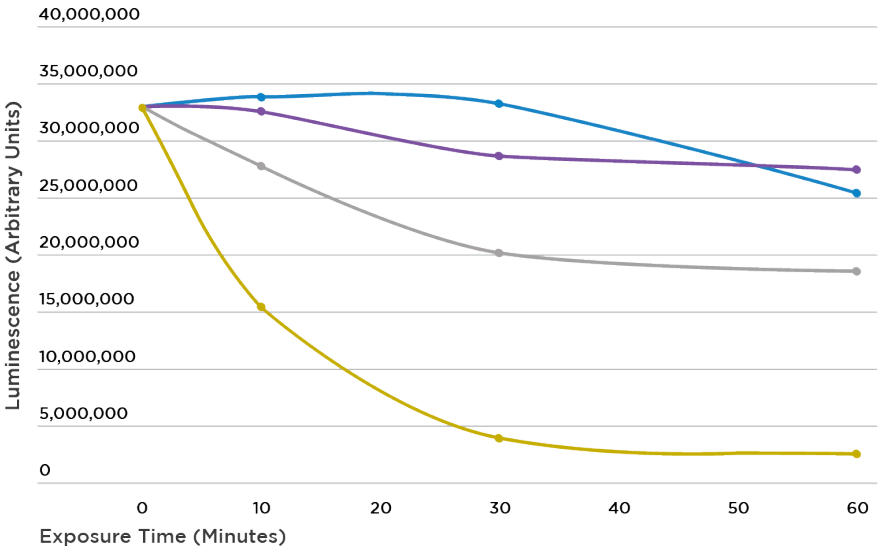
World Health Organisation List of Most Threatening Antibiotic Resistant Bacteria

PRIORITY 1: CRITICAL	RECCE® 327
Pseudomonas aeruginosa, carbapenem-resistant	✓ 1
Enterobacteriaceae, carbapenem-resistant, ESBL-producing	✓ 2
Acinetobacter baumannii, carbapenem-resistant	✓ 3
PRIORITY 2: HIGH	
Enterococcus faecium, vancomycin-resistant	✓ 4
Staphylococcus aureus, methicillin-resistant, vancomycin-intermediate and resistant	✓ 5
Helicobacter pylori, clarithromycin-resistant	✓ 6
Neisseria gonorrhoeae, cephalosporin-resistant, fluoroquinolone-resistant	✓ 7
Campylobacter spp., fluoroquinolone-resistant	NOT TESTED
Salmonellae, fluoroquinolone-resistant	NOT TESTED
PRIORITY 3: MEDIUM	
Streptococcus pneumoniae, penicillin-non-susceptible	✓ 8
Haemophilus influenzae, ampicillin-resistant	NOT TESTED
Shigella spp., fluoroquinolone-resistant	NOT TESTED

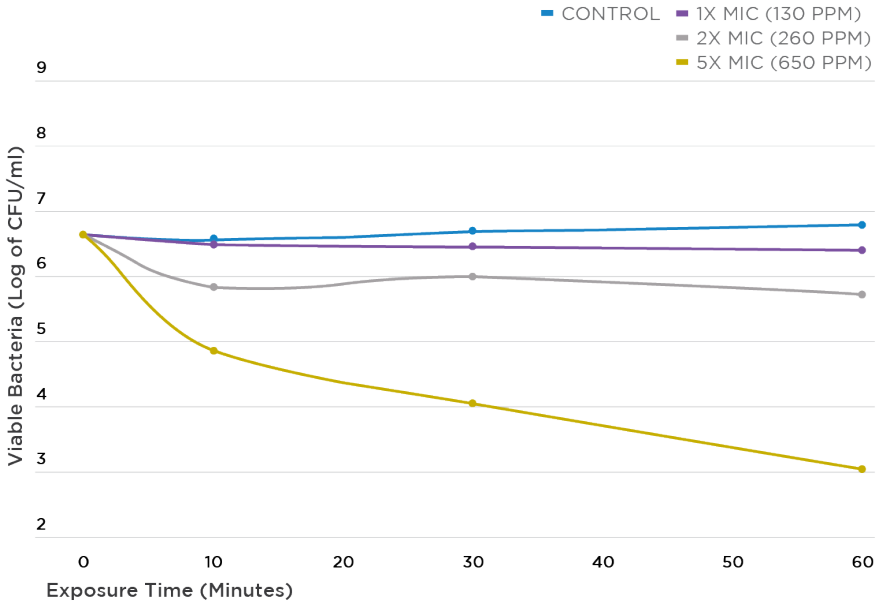
1 Active *in vitro* against Recce's own superbug of this bacterium
2 Active *in vivo* against a member of this family CRE *E. coli*
3 Active *in vitro* and against superbug variant CRAB
4 Active *in vitro* against a very closely related species, *Enterococcus faecalis*
5 Active both *in vitro* and *in vivo* against MRSA, Methicillin-resistant *S. aureus*
6 Active both *in vitro* and *in vivo* against three strains (2 of which were superbugs)
7 Active *in vitro* (superbug not available)
8 Active *in vitro* against related superbug *Klebsiella pneumoniae*
• List as of 2017

RECCE® 327 activity in 10% LB: *E. coli**

ATP Levels in *E. coli*



Viability: *E. coli* ATCC 25922



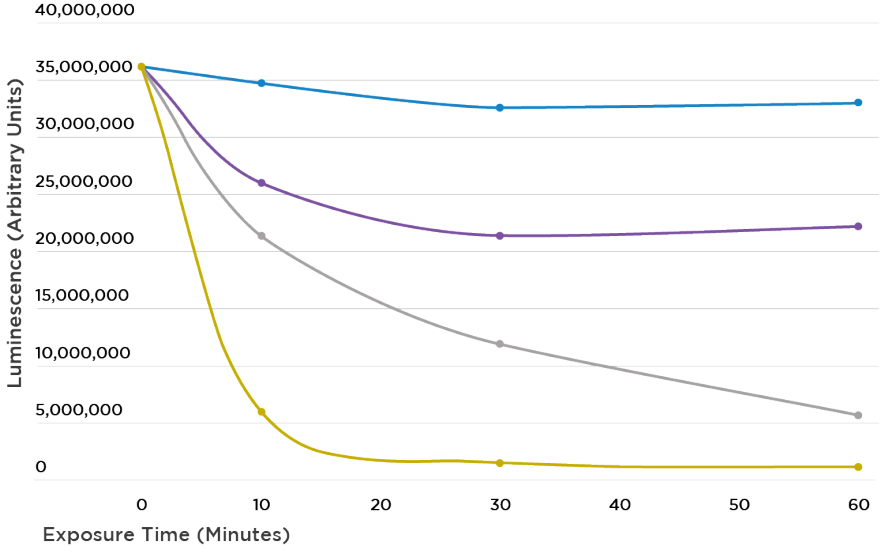
"R327 is killing all the cells in that culture within an hour"

Marc Sharp, PhD,
Chief Scientific Officer, Linnaeus Bioscience

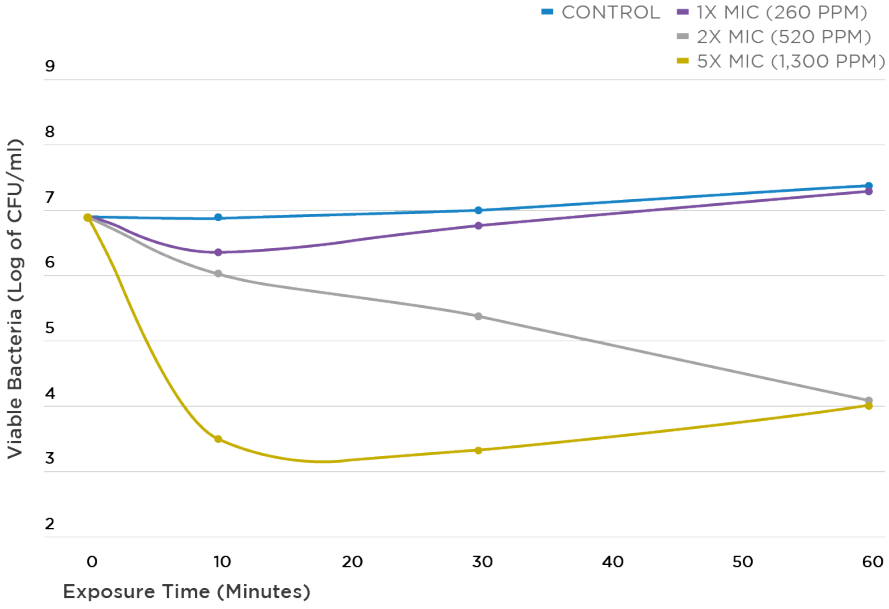
**Originally isolated from a human clinical sample collected in Seattle and WA (1946). It is of serotype O6 and biotype 1*
**ATCC 25922*

RECCE® 327 activity in 10% LB: *B. subtilis**

ATP Levels in *B. subtilis*



Viability:*B. subtilis* PY79



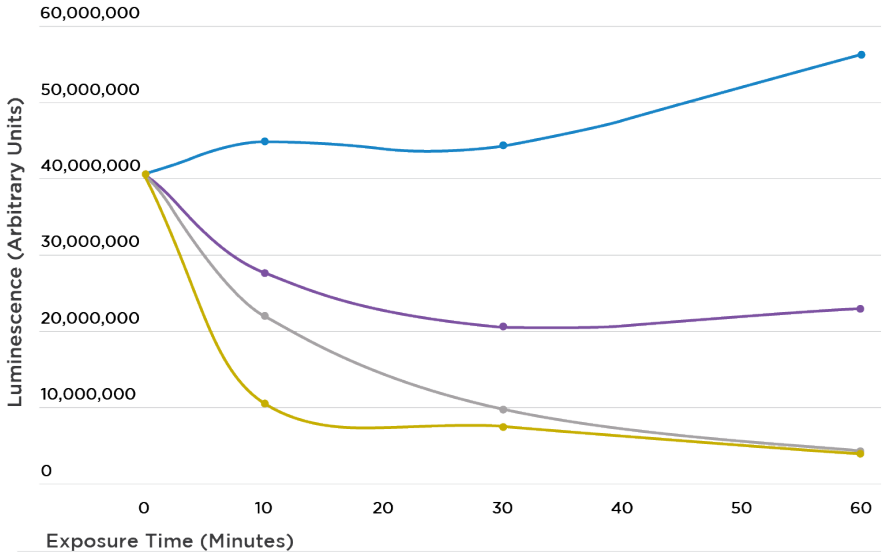
"Rapid decrease in ATP levels when you treat with R327"

Marc Sharp, PhD,
Chief Scientific Officer, Linnaeus Bioscience

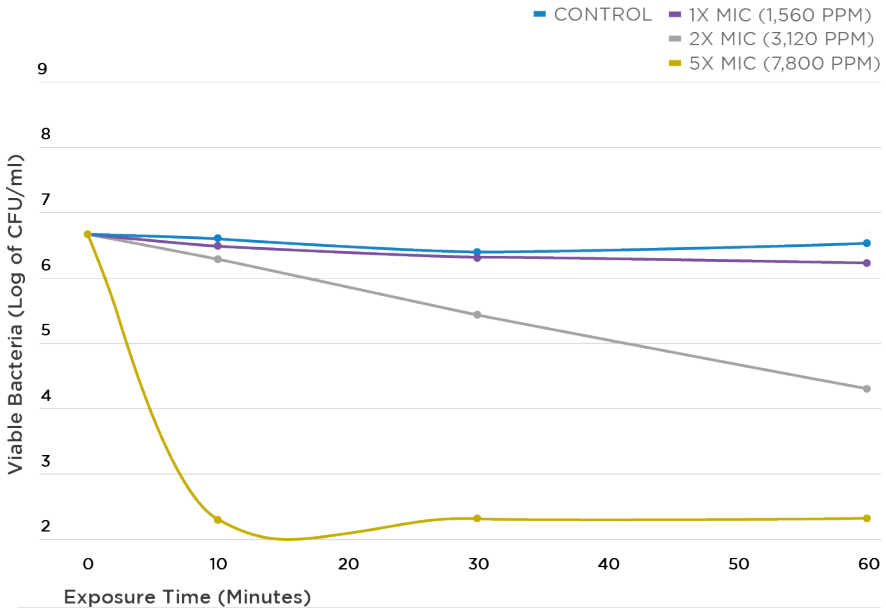
*Prototrophic laboratory strain that has been highly used for studying a wide variety of cellular pathways

RECCE® 327 activity in 10% LB: *P. aeruginosa**

ATP Levels in *P. aeruginosa*



Viability: *P. aeruginosa* PA01



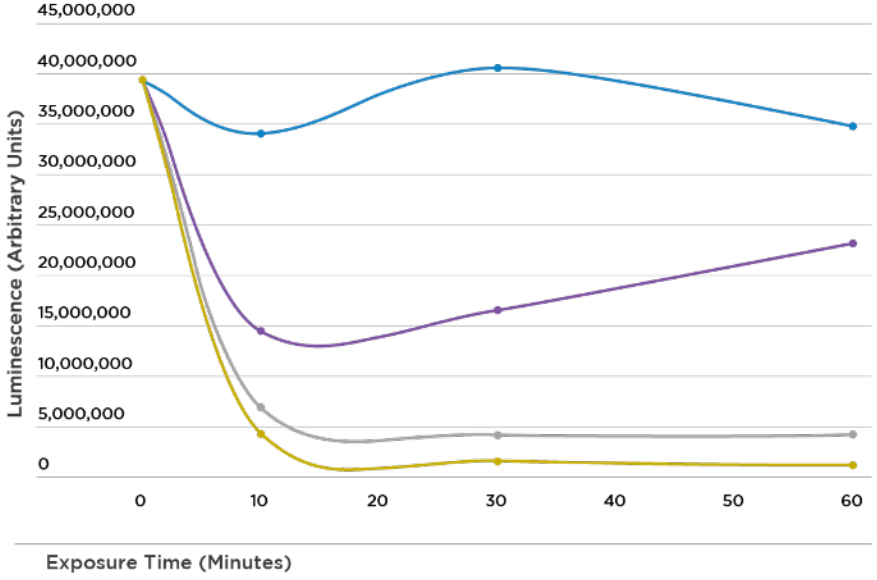
"Extremely resistant pathogen, very few drugs affect this pathogen and we're seeing again very strong effects from R327"

Marc Sharp, PhD,
Chief Scientific Officer, Linnaeus Bioscience

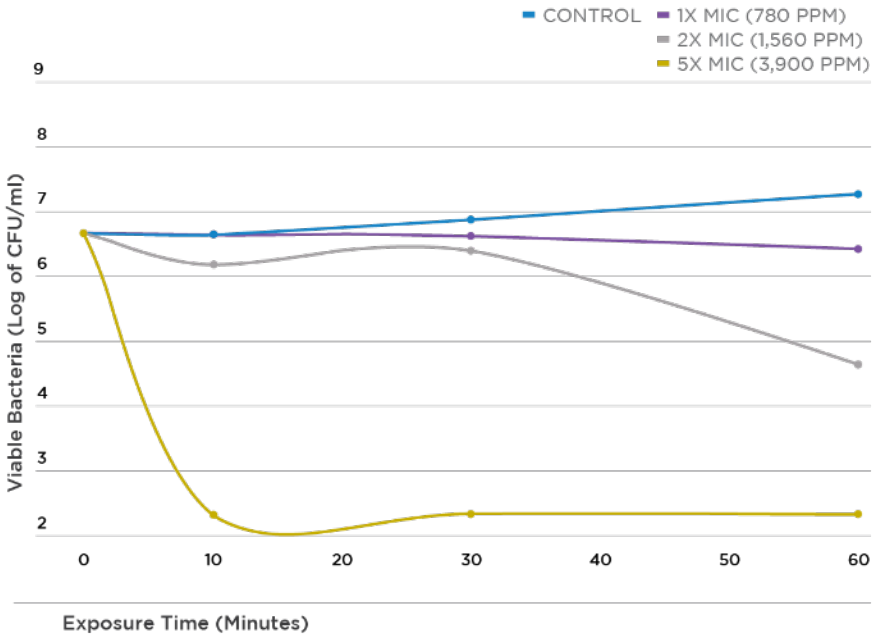
**Isolated from human wound PA01*

RECCE® 327 activity in 10% LB: *A. baumannii**

ATP Levels in *A. baumannii*

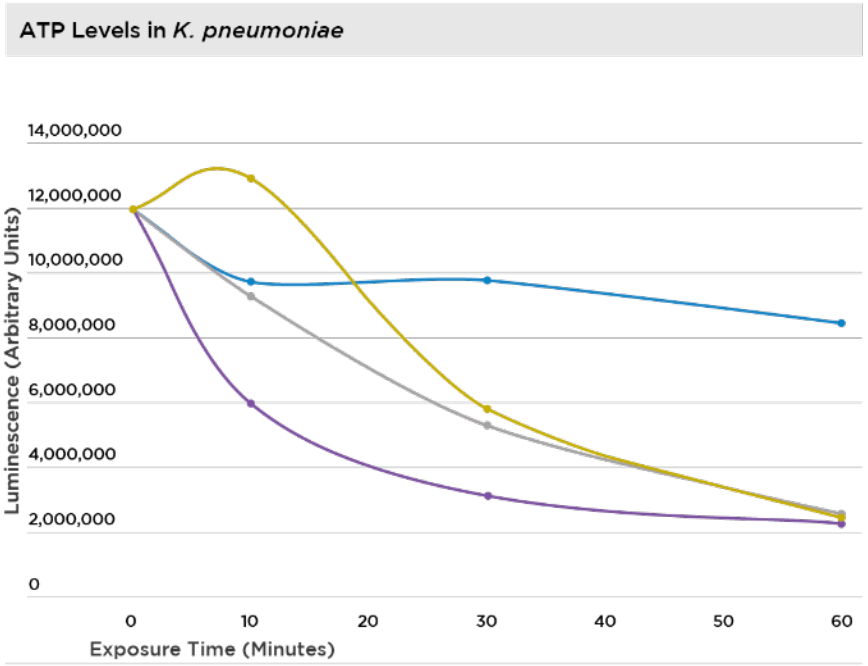


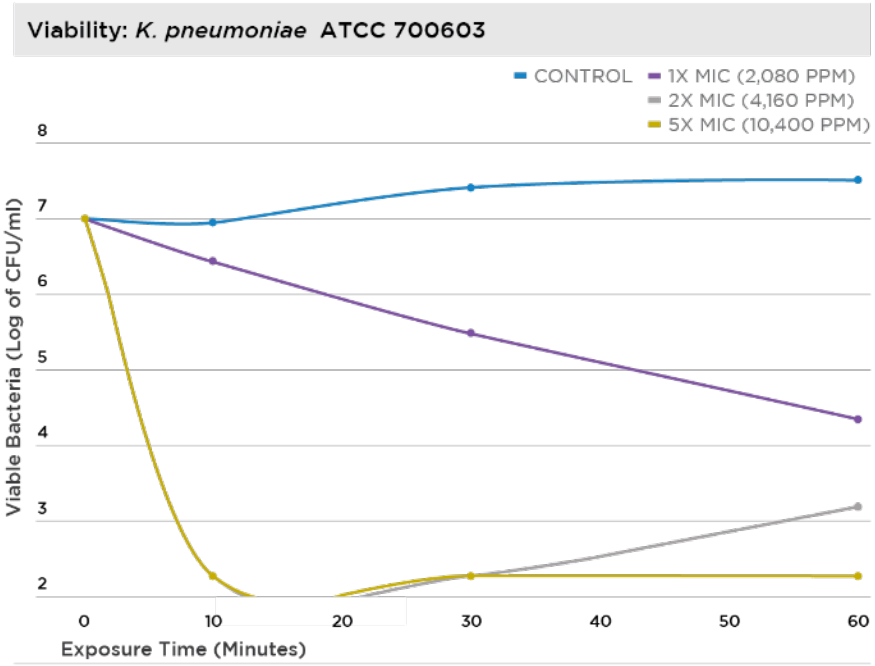
Viability: *A. baumannii* ATCC 17978



**Isolated from a fatal case of meningitis in a 4-month-old human*
**ATCC 17978*

RECCE® 327 activity in 10% LB: *K. pneumoniae**





"Very significant effect as quick as we can test this, within 10 minutes of treatment you're seeing very strong decreases"

Marc Sharp, PhD,
Chief Scientific Officer, Linnaeus Bioscience

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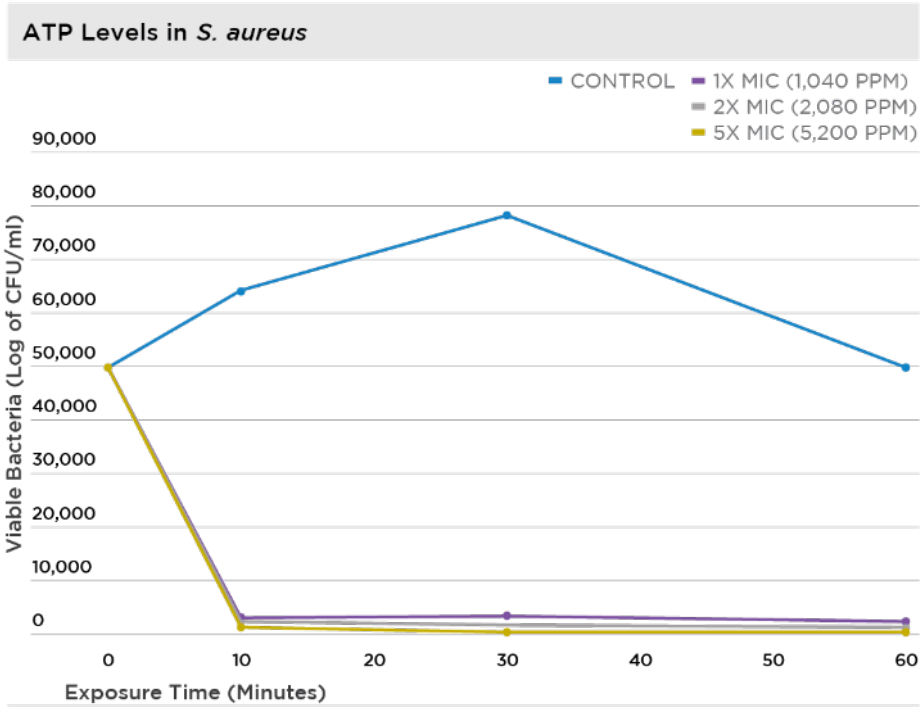
**Isolated from urine from hospitalised patient*
**ATCC 700603*

RECCE® 327 activity in 10% LB: *S. aureus* XEN36*



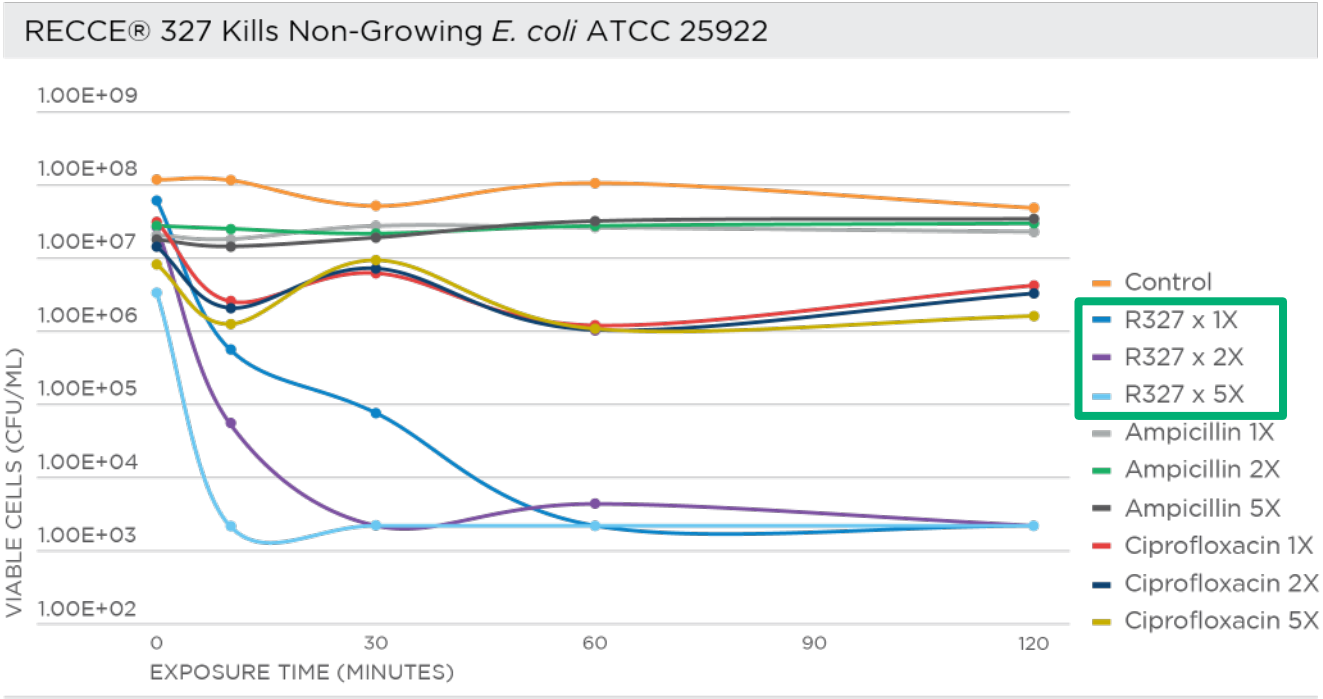
"Very rapid decrease in ATP levels, correlated with a very rapid decrease in viable cell counts"

Marc Sharp, PhD,
Chief Scientific Officer, Linnaeus Bioscience

recce.com.au

**Staphylococcus aureus Xen36 was derived from the parental strain Staphylococcus aureus ATCC 49525 (Wright), a clinical isolate from bacteraemia patient.*

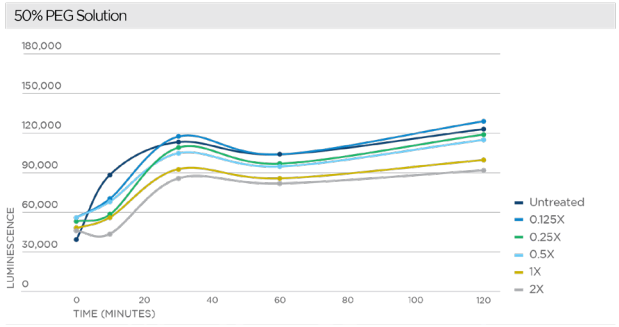
RECCE® 327 rapidly kills non-growing *E. coli*

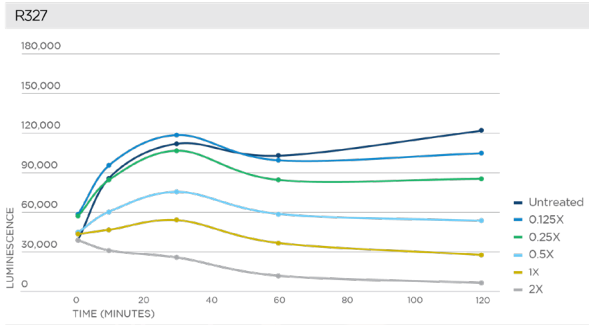


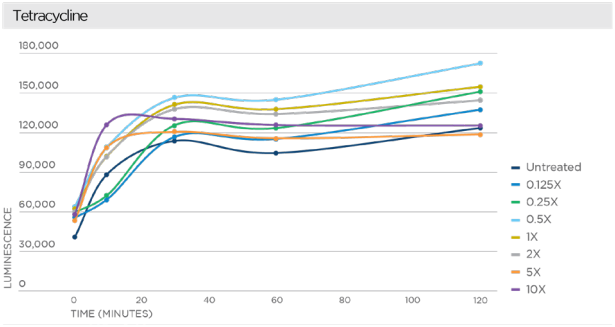
"Many antibiotics will not kill non-growing cells… R327 kills non growing cells and kills them very rapidly and irreversibly"

Marc Sharp, PhD,
Chief Scientific Officer, Linnaeus Bioscience

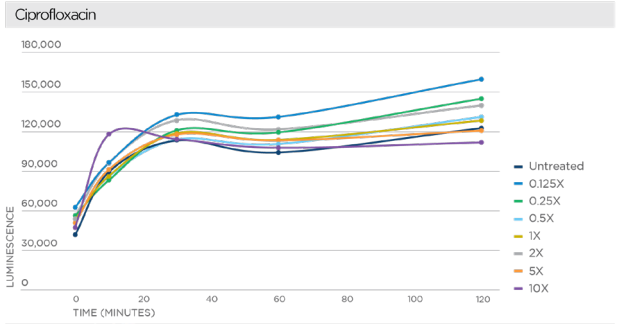
RECCE® 327 efficiently kills *E. coli* in a Biofilm

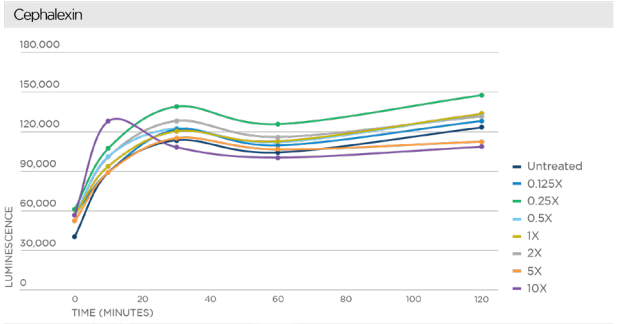


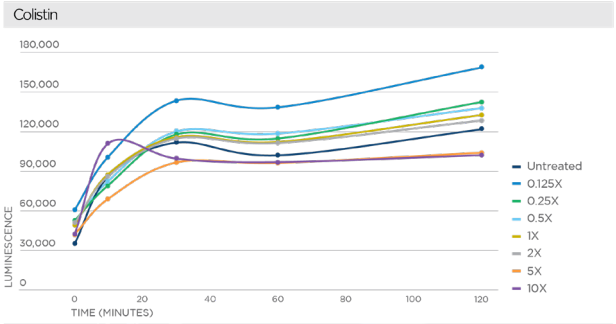




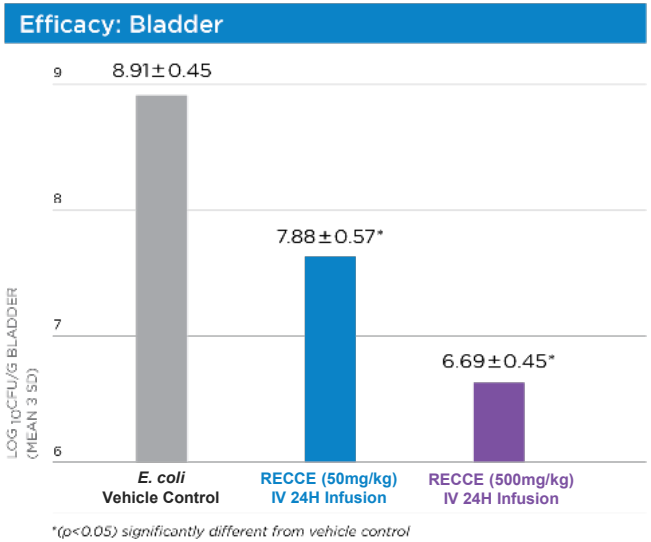
Unlike many common antibiotics, ***R327 disrupts cellular bioenergetics and efficiently kills E. coli in a biofilm***

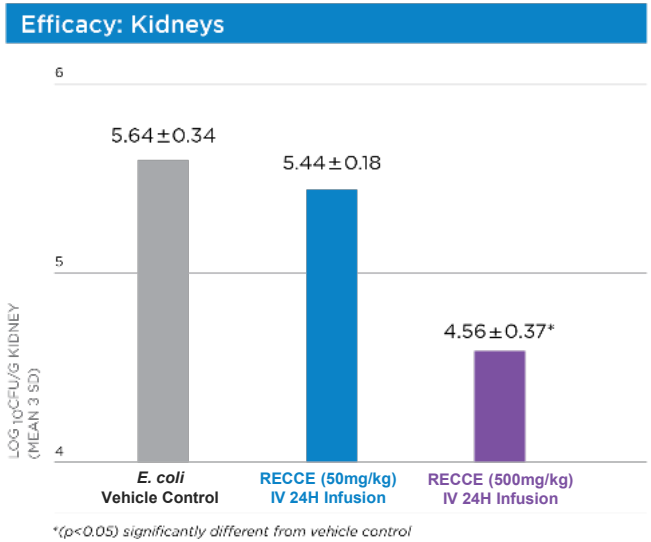






Pre-Sepsis UTI and Kidney Models in Rats





Single 24-hour intravenous infusion

Group 1 – *E. coli* infection + vehicle control

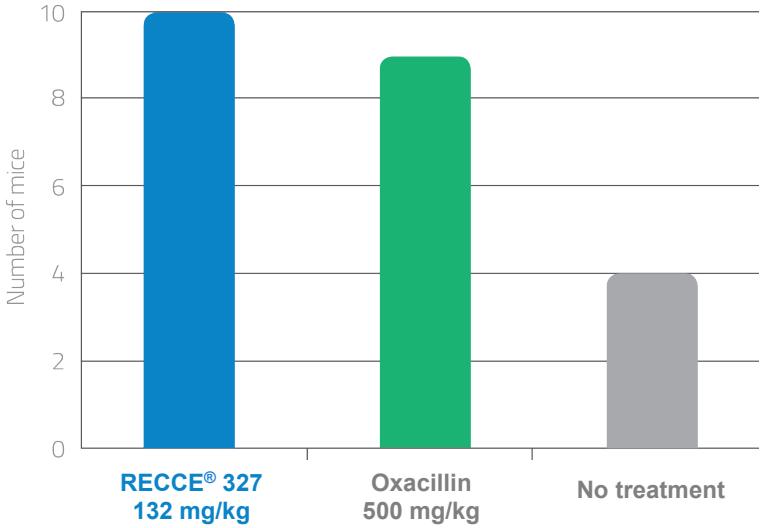
Group 2 – *E. coli* infection + R327 50mg/kg

Group 3 – *E. coli* infection + R327 500mg/kg

- **R327 as a treatment of Kidney and other UTIs caused by *E. coli*, (pre-sepsis) 'early stage'**
- **R327 showed dose dependent antibacterial effect in the kidney and bladder at 50mg/kg and 500mg/kg when compared to vehicle control (p<0.050).**
- **Rats treated with RECCE® 327: no adverse clinical signs were observed**

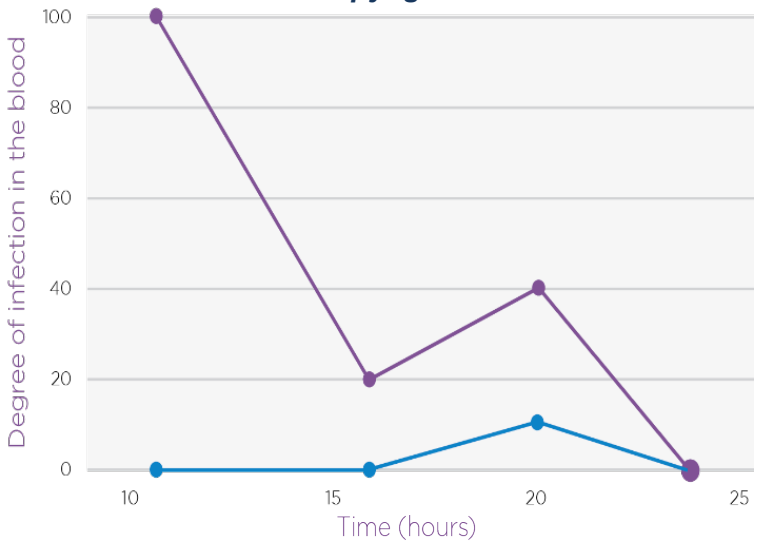
RECCE® 327 – Curative & Preventative IV Studies*

Number of mice that survived Sepsis from *S. aureus (superbug)*



- **All ten mice treated with RECCE® antibiotic survived**
- Nine mice treated with efficacious dose of Oxacillin (500 mg/kg) survived
- Four mice that had no treatment at all, survived

Infection in mice from *S. pyogenes*



- **One group of ten mice** were administered a 167 mg/kg dose of RECCE® 327 at 0 hours. **Second group** received no antibiotic.
- Both groups inoculated with the *S. pyogenes* burden into the bloodstream.
- Mice results first monitored after 12 hours allowing bacteria to develop and establish an infection.
- Bacteria in the blood were rapidly killed and unable to establish an infection in the kidneys of mice who received RECCE® 327.

*** Results from an independent laboratory in USA**

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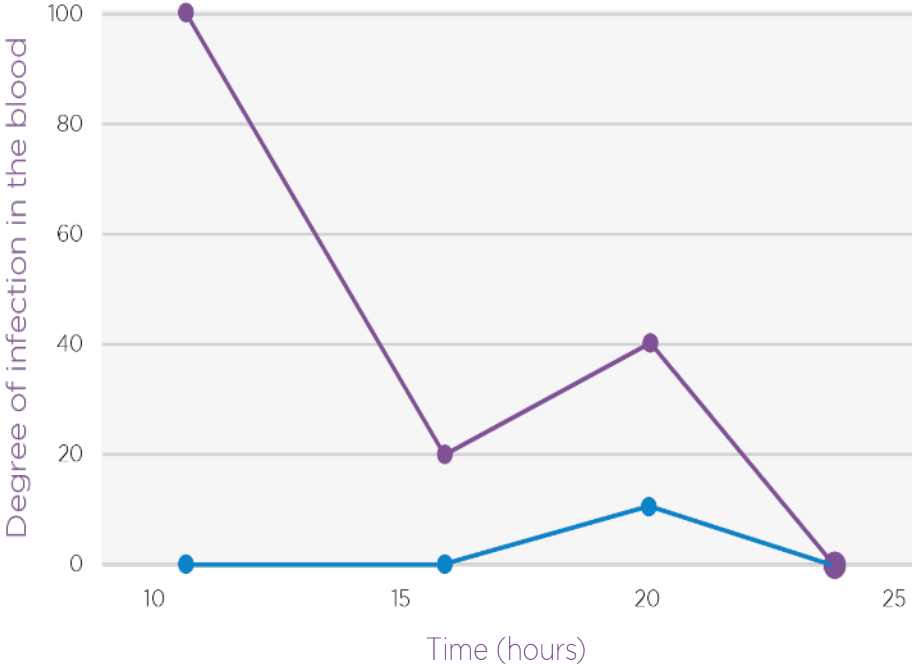
RECCE® 327 – Infection IV Preventative Study*

To examine the prophylaxis potential of RECCE® 327, a study was carried out using mice that were infected with *S. pyogenes*:

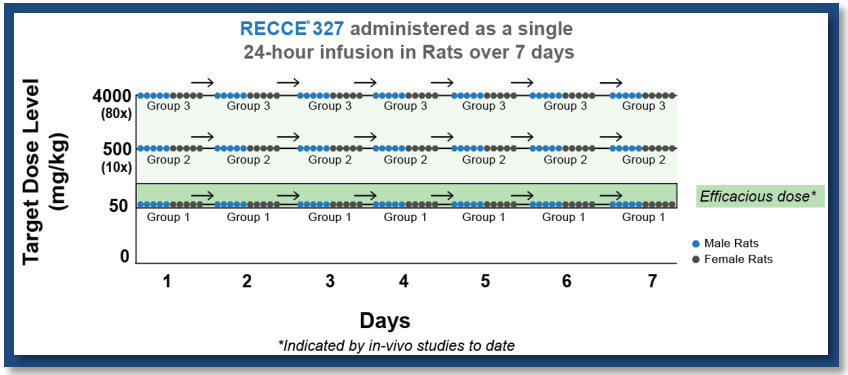
- **One group of ten mice** were administered a 167 mg/kg dose of RECCE® 327 at 0 hours. **Second group** received no antibiotic.
- Both groups were then inoculated with the same *S. pyogenes* burden into the bloodstream.
- Mice results were first monitored after 12 hours post-inoculation to allow the bacteria enough time to develop and establish an infection.
- 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.
- The control group's *S. pyogenes* appeared to clear from the blood after 12 hours, HOWEVER bacteria rapidly colonise in the kidneys (the blood's natural filter), which commonly leads to catastrophic kidney failure and death.

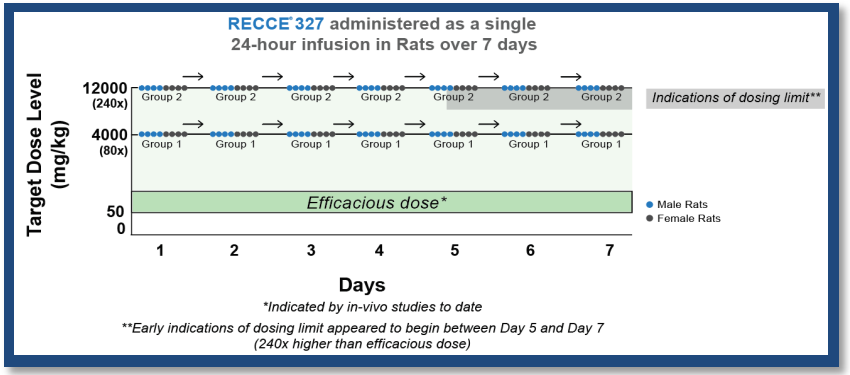
Infection in mice from *Streptococcus pyogenes*



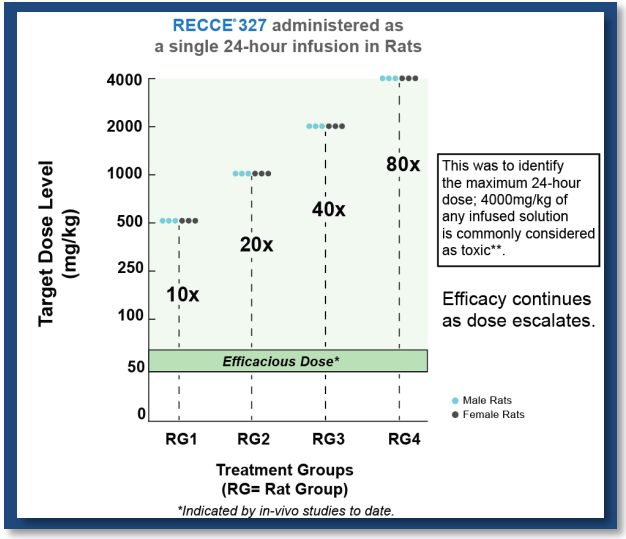
*** Results from an independent laboratory in USA**

Single Dose and Range-Finding Repeat Dosing - Rats





- **No Observed Adverse Effect Level (NOAEL) of 24-hour 500mg/kg (10x indicated efficacious dose)**
- Phase Ia (24-hour), Phase Ib (24-hour over 7 days)
  - A separate single 24-hour intravenous infusion administration of RECCE® 327 up to 12,000 mg/kg over the course of 7-days was carried out.
  - Results of up 12,000 mg/kg/day was well tolerated from Days 1 to 4 (inclusive); with no mortalities or clinical signs.
- 24-hour dosing up to 4,000 mg/kg (80x indicated efficacious dose) in Dogs well tolerated.
- RECCE® 327 is indicated to be efficacious from as little as 50mg/kg and here shows tolerability can be sustained over at least 7 days of continuous daily exposure at doses up to and including 500 mg/kg.



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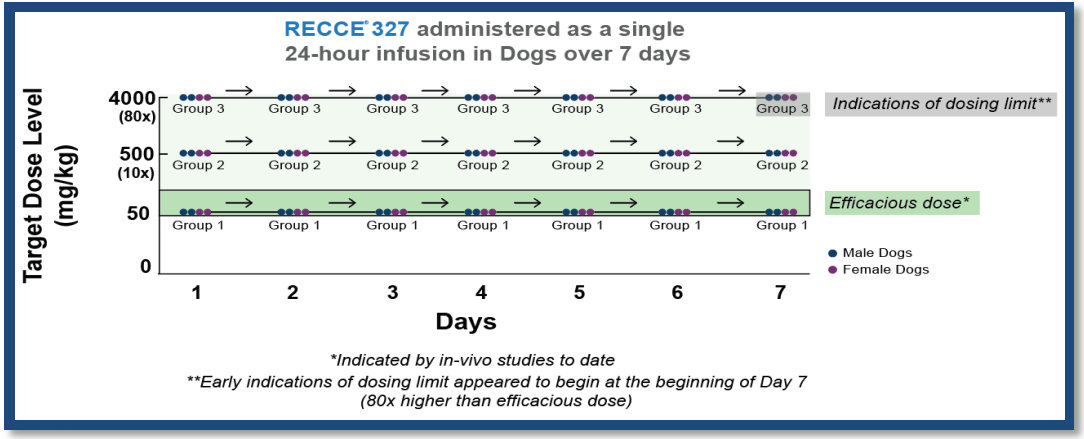
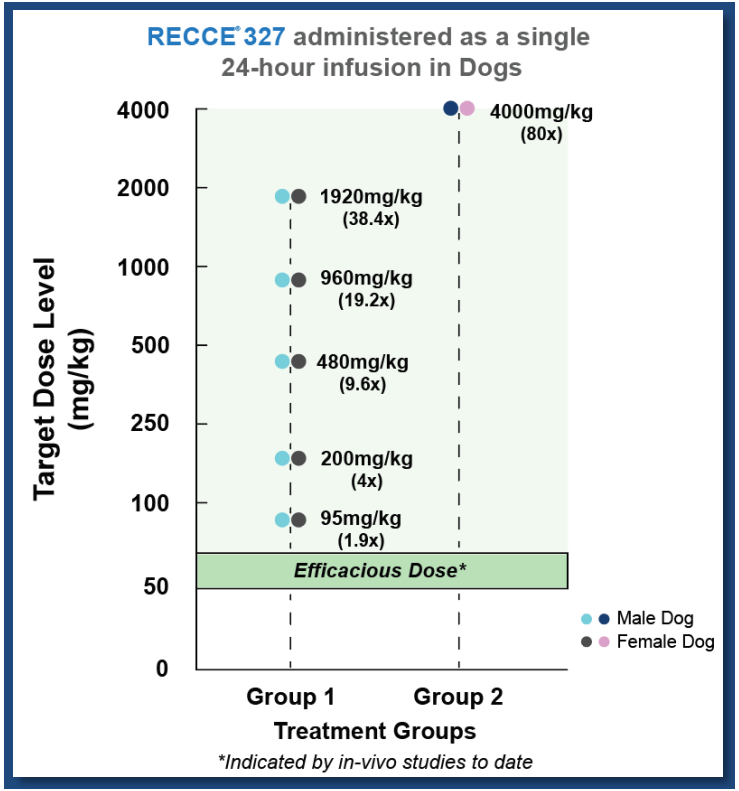
Single Dose and Range-Finding Repeat Dosing - Dogs

- **No Observed Adverse Effect Level (NOAEL) of 24-hour 500mg/kg (10x indicated efficacious dose)**
- Phase Ia (24-hour), Phase Ib (24-hour over 7 days)
- A single 24-hour intravenous infusion administration of RECCE® 327 up to 4000 mg/kg and 7-day continuous intravenous infusion administration of RECCE® 327 up to 500 mg/kg/day were well tolerated; with no mortalities, clinical signs, changes in body weight, coagulation, clinical chemistry or salient macroscopic abnormalities.
- RECCE® 327 is indicated to be efficacious from as little as 50mg/kg
- Therapeutic dose window appears considerably wider than Vancomycin and other antibiotics.



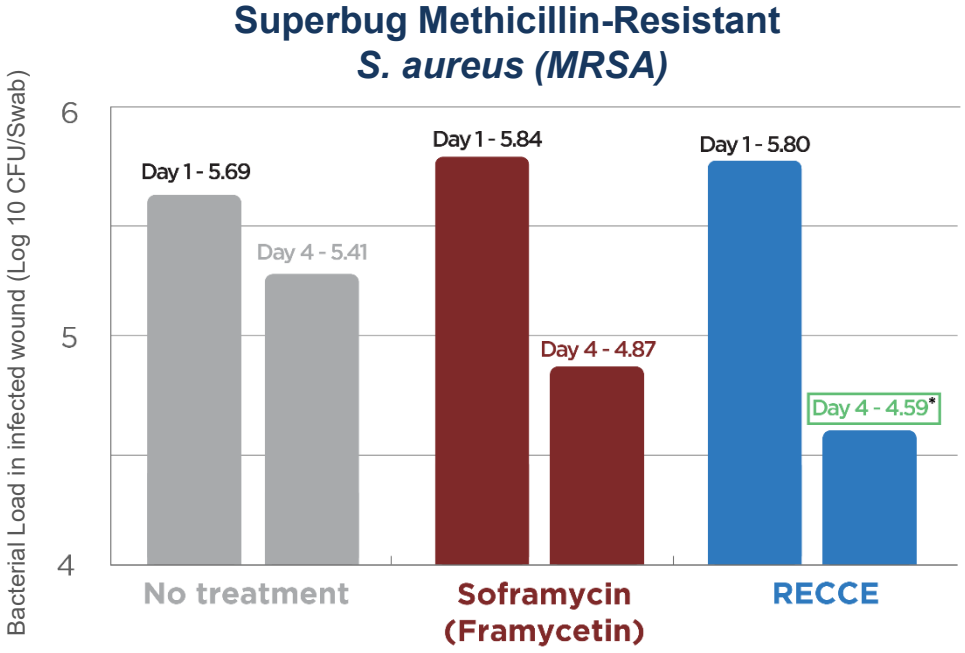


Topical Efficacy – Rat Bacterial Wound Infection

- **Group 1** – Burn wound with infection, no treatment – sterile topical saline, once daily.
- **Group 2** – Burn wound with infection + Market drug – Soframycin, twice daily.
- **Group 3** – Burn wound with infection + RECCE® 327 – topical once daily.

The Study Director noted: "***RECCE® 327*** *(100 µl (19.15 mg/ml), topical, once daily over three days)* ***showed significant reduction in bacterial load on day four*** *when compared to day one, whereas there was no significant reduction in bacterial load in the vehicle control (p>0.05)."*

"***Soframycin*** *(30 mg, topical, twice daily, Q=12hr, over three days),* ***the current standard of care antibiotic did not show significant efficacy*** *on day four when compared to day one although the mean load was lower."*



Note: Soframycin is a Marketed topical antibiotic for the treatment of bacterial infections in burns and wounds. It was chosen for its known activity against MRSA.

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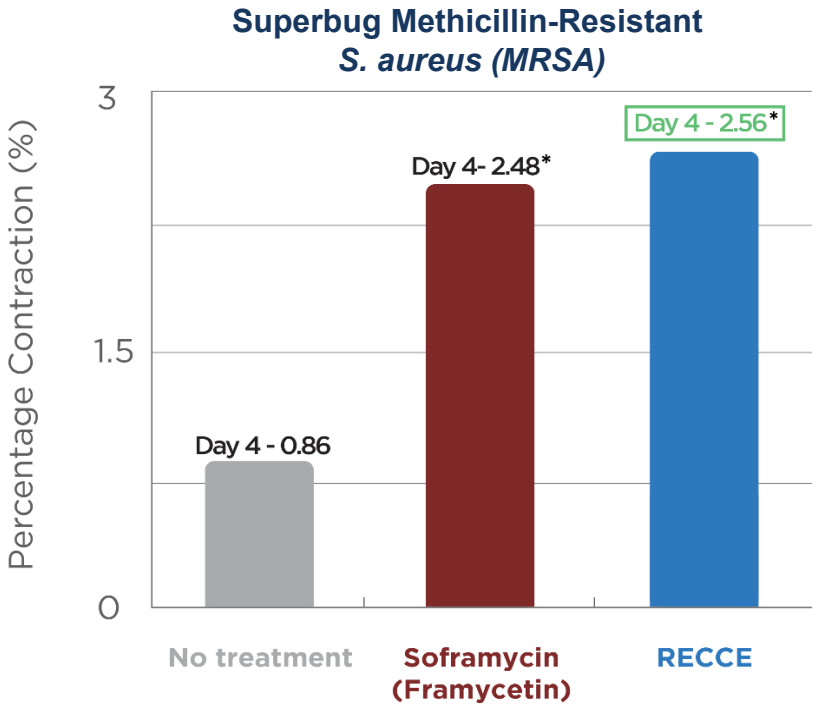
* Significantly lower than Day 1

Results from an independent laboratory in USA

Topical Efficacy – Rat Wound Contraction (healing)

- **Group 1** – Burn wound with infection, no treatment – sterile topical saline, once daily.
- **Group 2** – Burn wound with infection + Market drug – Soframycin, twice daily.
- **Group 3** – Burn wound with infection + RECCE® 327 – topical once daily.

The Study Director noted: "***RECCE® 327*** (100 µl (19.15 mg/ml), topical, once daily, over three days), and **Soframycin** (30 mg, topical, twice daily, Q=12hr, over three days) ***showed a significant reduction wound on day four*** ($p<0.05$) when compared to day one, when compared to the vehicle control."



Note: Soframycin is a topically marketed antibiotic for the treatment of bacterial infections in burns and wounds. It was chosen for its known activity against MRSA.

*Significantly different from vehicle control ($p<0.05$, 1-way ANOVA
Results from an independent laboratory in USA

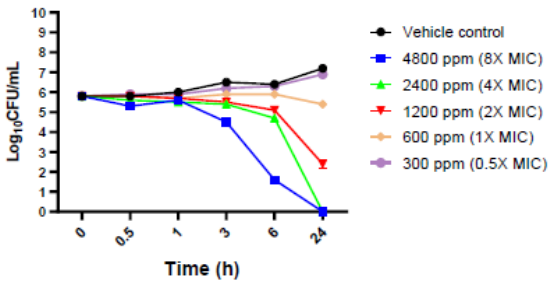
RECCE® 327 Efficacy Against Necrotizing Fasciitis

- R327 shown to reduce deadly **'flesh-eating'** bacterial count **Below Limit of Quantification (BLOQ)** within 24 hours, at varying concentrations
- R327 **BLOQ** efficacy as early as 30 minutes in *C. perfringens* – a leading bacterial cause of myonecrosis (gas gangrene)
- **99.9% (3-log) bacterial reduction achieved in all bacteria tested, at various concentrations**
- Data demonstrates R327's potential against bacterial infections that thrive in nil/low oxygen environments i.e. diabetic wounds/ulcers infections

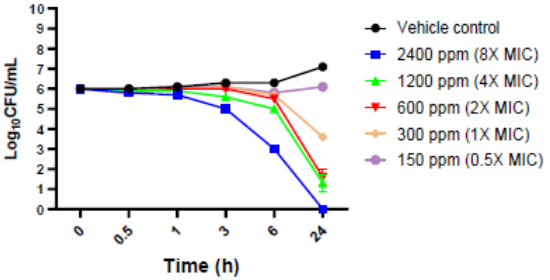
Compound	Test Strain	Test Concentration (ppm)	Time of 3-log reduction (hrs)	BLOQ* (24hr count)
R327	*S. pyogenes* - susceptible strain	4800 (8x MIC)	6 to 24	✓
		2400 (4x MIC)	24	✓
		1200 (2x MIC)	24	-
	S. pyogenes - erythromycin-resistant strain	2400 (8x MIC)	6 to 24	✓
		1200 (4x MIC)	24	-
		600 (2x MIC)	24	-
	C. perfringens	4000 (8x MIC)	0.5 to 24	✓
		2000 (4x MIC)	0.5 to 24	✓
		1000 (2x MIC)	3 to 24	✓
		500 (1x MIC)	24	✓

Time of the 3-log[10] reduction is the time point in which CFU counts at the respective test condition is reduced relative to the initial CFU counts by ≥3-log[10]. The initial CFU counts are at the start, time 0, of the assay.

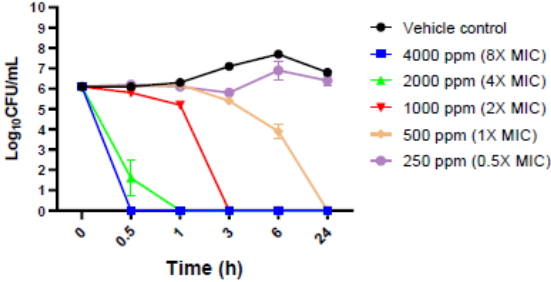
S. pyogenes ATCC 19615 with Recce 327
Time-kill curve (average)



S. pyogenes BAA-946 with Recce 327
Time-kill curve (average)

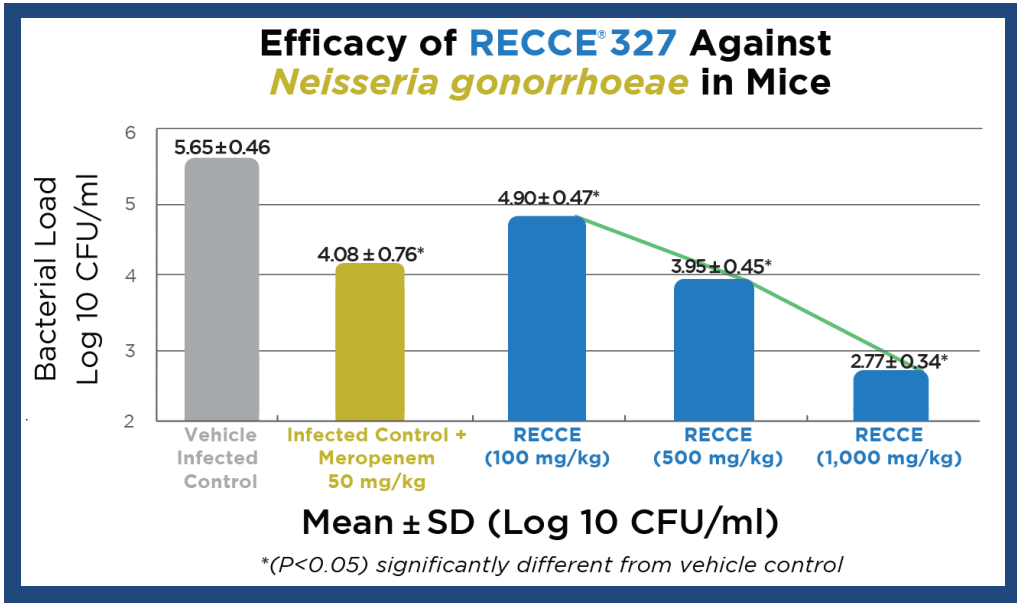


C. perfringens ATCC 13124 with Recce 327
Time-kill curve (average)



RECCE® 327 Efficacy Against *Neisseria gonorrhoeae*

- **Statistically significant reduction of *Neisseria gonorrhoeae* in reproductive organs of female mice.**
- **R327 outperformed market approved drug Meropenem in most instances.**
- *Neisseria gonorrhoeae*, a species of Gram-negative bacteria, and the second most common sexually transmitted infection (STI) globally.
- **R327 showed significant dose dependent antibacterial effect in vaginal load at 100, 500 and 1000 mg/kg** given by IV bolus
- Meropenem's high rates of bacterial resistance have recently led to restriction of its use strictly reserved for infections caused by resistant organisms.
- ***Potential of R327 to not only become a potent broad-spectrum antibiotic but most critically to continue working against antibiotic resistant bacteria or superbugs, even with repeated use***

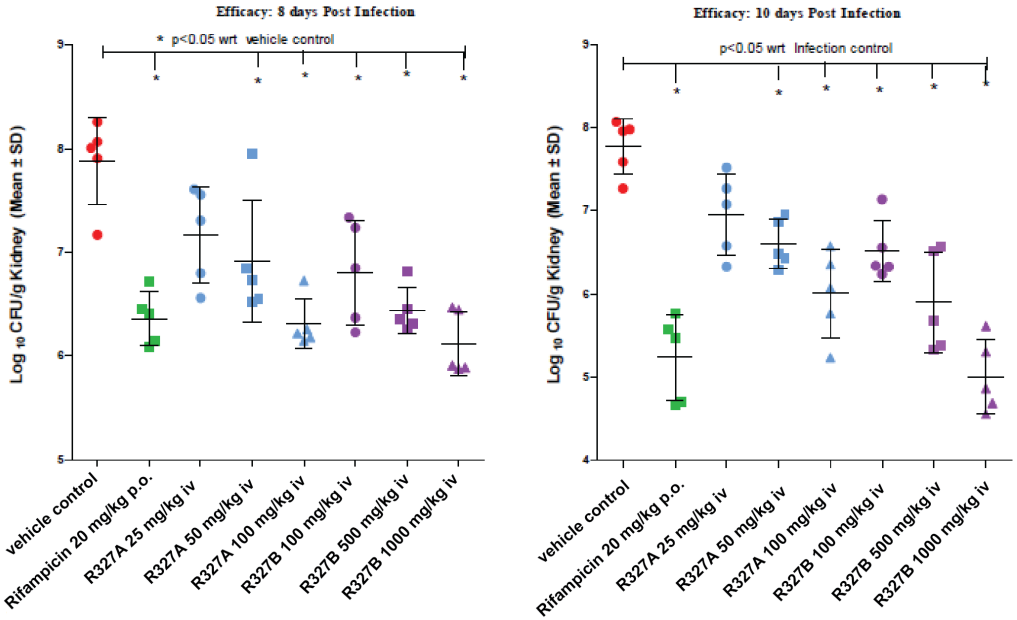


Mycobacterium fortuitum

M. fortuitum is accepted as a substitute organism to test for proof-of-concept efficacy and to provide a model of Tuberculosis infection in animals

- The aim of the study was to evaluate the efficacy of R327A and R327B against *Mycobacterium fortuitum* (ATCC6841TM) in the mouse intravenous infection model.
- **Both R327A and R327B showed dose dependent antibacterial effect in Kidneys on days 8 and 10.**
- R327A - **Significant decrease in bacterial load was observed** with 50 and 100 mg/kg on days 8 and 10 Post Infection (PI) (P<0.05) when compared to the corresponding vehicle controls.
- R327B - **Significant decrease in bacterial load was observed** with 100, 500 and 1000 mg/kg on days 8 and 10 PI (P<0.05) when compared to the corresponding vehicle controls.
  - **Day 10 PI, R327B achieved a superior bacterial load log reduction (3-logs (99.9%) = "bactericidal effect") than the optimally dosed Positive Control (Rifampicin)**
- **The decrease in bacterial load in kidneys also correlated with decrease in the number of kidney lesions.**

Time course of bacterial load in kidneys of mice
treated with reference and test compounds



Mycobacterium abscessus

Study 1: Successfully demonstrated activity (MIC) of R327 against *M. abscessus* in culture

Study 2: Investigated the effect of R327 against *M. abscessus* infecting macrophages

- In the human lung, *M. abscessus* infect macrophages (type of immune cell)
- Inside these cells, the bacteria are protected from immune attack
- Many antibiotics cannot enter cells and therefore do not reach these *M. abscessus*

Human stem cell-derived macrophages (used due to their physiological similarity to macrophages in the human lung) were infected with *M. abscessus* ATCC 19977 then treated with R327.

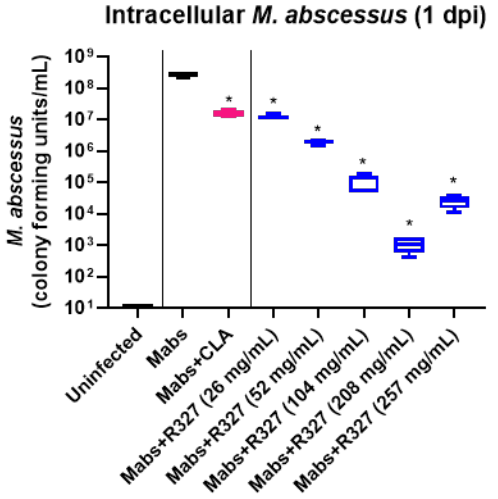
1 and 3 days later, live *M. abscessus* inside the cells were quantified by colony-forming assay.

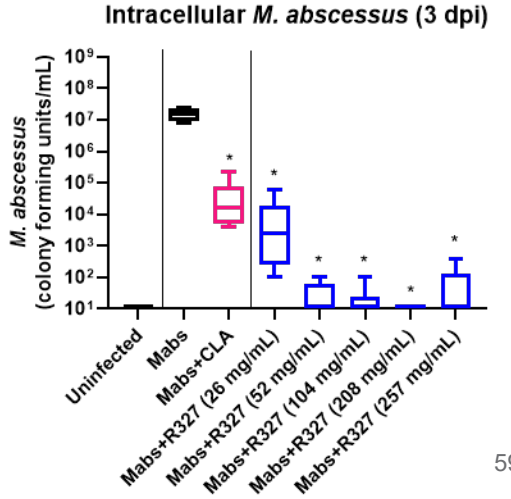
R327 was extremely effective at killing intracellular *M. abscessus*

- No toxic effect on the macrophages
- Dose-dependent killing of *M. abscessus* with eradication of bacteria obtained at 3 days post infection (dpi)

R327 superior to Clarithromycin positive control

- Clarithromycin was one of the rare antibacterial agents used in the 1990s with some success and became the treatment of choice[1]





Mycobacterium abscessus

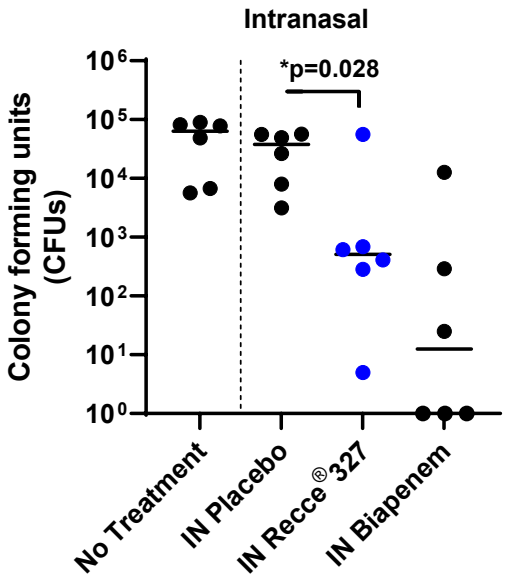
Study 3: Examine the efficacy of R327 treatment against *M. abscessus* lung infection in mice

In a pilot study (unoptimized conditions), mice infected in their lungs with *M. abscessus* were treated with R327, nasally (intranasal), twice daily for five days.

Levels of *M. abscessus* in the lungs were then quantified by colony-forming assay.

- **No adverse events were observed in the mice**, while treating a lung infection
- Nasal R327 treatment **significantly reduced *M. abscessus* levels**
- Despite using unoptimized dose and delivery, efficacy of R327 was only slightly inferior to that of the positive control antibiotic, Biapenem

Pulmonary *M. abscessus*



IN = intranasal

Mycobacterium abscessus - Summary

M. abscessus has emerged as one of the most important lung pathogens in cystic fibrosis

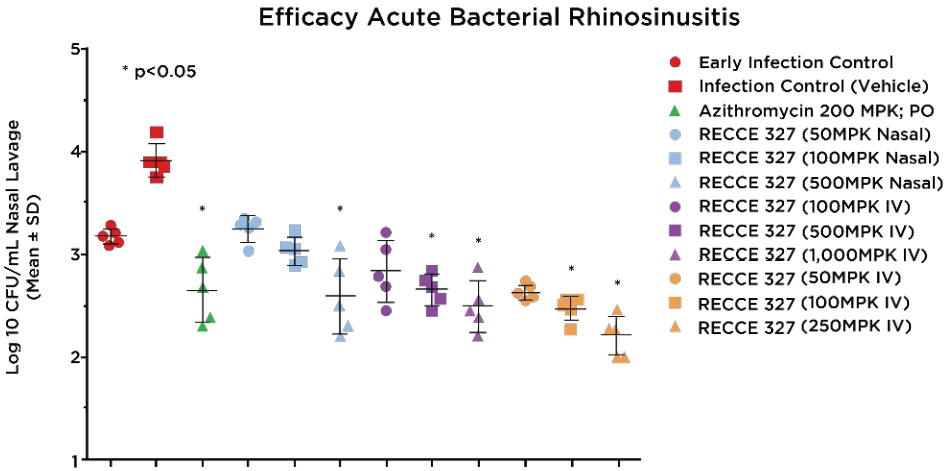
- *Major driver of disease progression*
- *Contraindication for end-stage lung transplantation*
- *Current treatments ineffective and toxic*

R327

- **No toxicity observed against treated (physiologically relevant) human macrophages, or in infected mice**
- **Very good activity against intracellular *M. abscessus* within human macrophages**
  - Complete eradication of infection achieved
  - Able to **penetrate cells** and **kill these bacteria inside macrophages**
- **Proof of concept achieved in killing of *M. abscessus* infection in mice following nasal delivery**

Sinusitis Infection Efficacy – Rats

- **Positive sinusitis infection data indicated in animal study**
- Study supports broad spectrum potential of Recce's anti-infective compounds against *Streptococcus pneumoniae (S. pneumoniae)* for both nasal and intravenous administration
- R327 tested against marketed therapeutic alternative *in-vivo* in sinusitis study; independent study agreement anticipated



Group	Treatment	Clinical Observation
1	Early infection control (day1 post infection)	NAD
2	Infection vehicle control, twice daily, oral, 5 days	NAD
3	Positive Control (Azithromycin, oral, 200 mg/kg, twice daily, 5 days)	NAD
4	RECCE® 327 (Low dose, Nasal, 50 mg/kg, Twice daily, 5 days)	NAD
5	RECCE® 327 (Mid dose, Nasal, 100 mg/kg, Twice daily, 5 days)	NAD
6	RECCE® 327 (High dose, Nasal, 500 mg/kg, Twice daily, 5 days)	NAD
7	RECCE® 327 (Low dose, IV, 100 mg/kg, Twice daily, 5 days)	NAD
8	RECCE® 327 (Mid dose, IV, 500 mg/kg, Twice daily, 5 days)	NAD
9	RECCE® 327 (High dose, IV, 1000 mg/kg, Twice daily, 5 days)	NAD
10	RECCE® 327 (Low dose, IV, 50mg/kg, Twice daily, 5 days)	NAD
11	RECCE® 327 (Mid dose, IV, 100 mg/kg, Twice daily, 5 days)	NAD
12	RECCE® 327 (High dose, IV, 250mg/kg, Twice daily, 5 days)	NAD

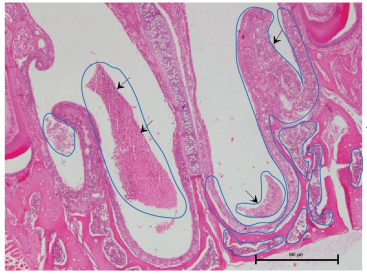
Efficacy Acute Bacterial Rhinosinusitis
NAD: No abnormality detected

This bacterium was chosen due to its immediate availability as a recognised sinusitis model

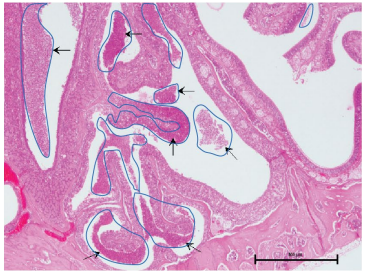
Sinusitis Infection Efficacy – Rats

Early Infection Control

Multiple Neutrophils

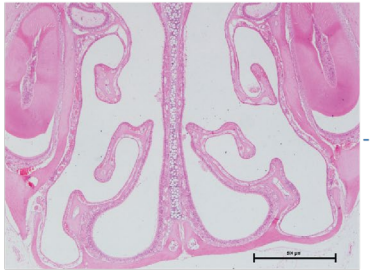


Multiple Neutrophils



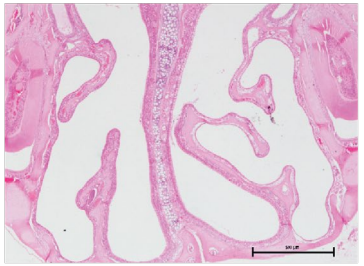
R327 IN* Low dose ✓

Healthy Sinus Cavities - No Abnormality Detected



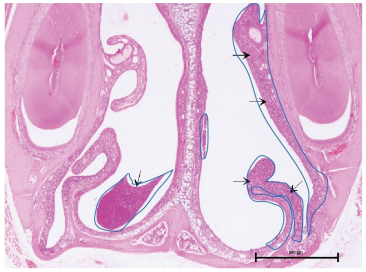
R327 IN* Low dose ✓

Minimal Neutrophils

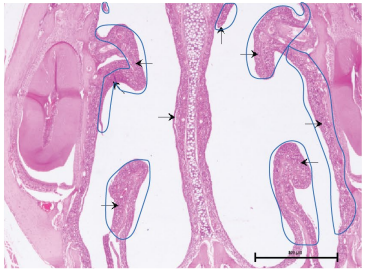


Positive Control IN* - Azithromycin

Multiple Neutrophils

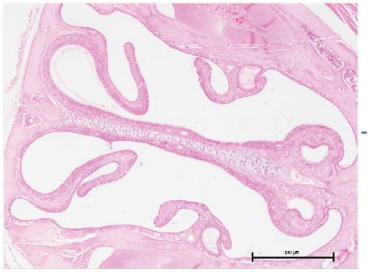


Multiple Neutrophils



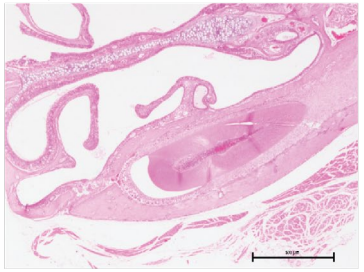
R327 IV* Low dose ✓

Healthy Sinus Cavities - No Abnormality Detected



R327 IV* Mid dose ✓

Healthy Sinus Cavities - No Abnormality Detected



* Intranasal ** Intravenous

The Company's RECCE® 327 compound showed significant antibacterial capability with no abnormalities detected and are expected to be subject to further expanded sinusitis studies in due course

Patient Case Study – Special Access Scheme

- Special Access Scheme (SAS) Category A notification was 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**.
- Patient X had suffered from sinusitis infections all of their adult life and had advanced to a multidrug-resistant *P. aeruginosa* sinusitis infection in their upper nasal eustachian tube.
- **Infection was unresponsive to all antibiotic treatments attempted** including ciproflaxin (negative side effects), Septrim Forte (twice daily) and Doxylin, including last-resort peripherally inserted central catheter (PICC Line)
- Patient X dosed according to a strict, dose-escalating protocol applying 5-10 drops per 20mL of R327 in saline solution, three times a day into the infected area.
  - 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 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 showed no detectable signs of *P. aeruginosa* infection and no abnormalities.

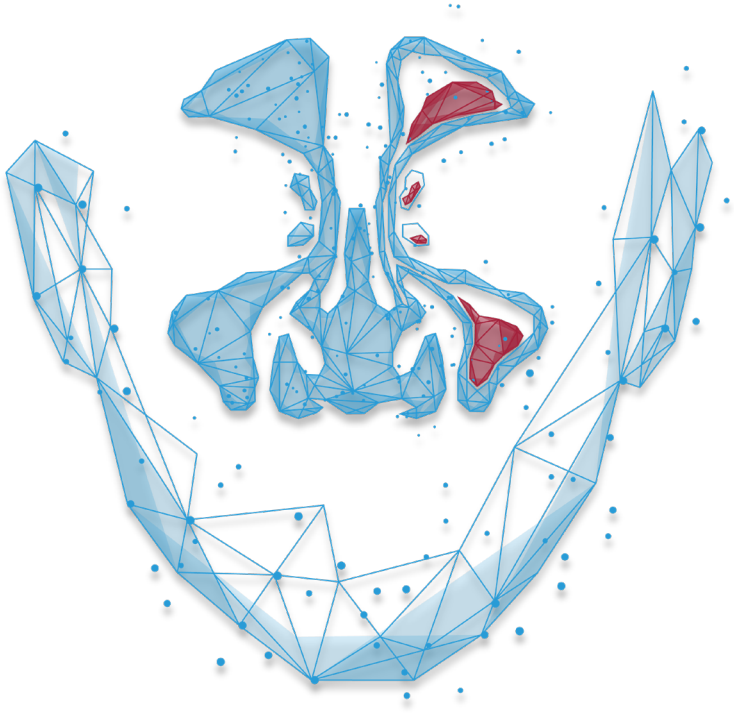


Image representation of infected sinus in humans – not actual patient

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 X not named for reasons of patient confidentiality

Empowering Clinicians with a New Class of Antibiotics

The need for new antibiotics has never been greater

- **Initial resistance to use** new approved drugs due to antibiotic resistance
- "**New antibiotics**, able to kill drug-resistant bacteria, is **essential** to saving modern medicine."
  - *Wellcome Trust*
- "**Lack** of **new antibiotics threatens** global efforts to contain drug-resistant infections."
  - *World Health Organization*

R327 addressing market need

- **R327 does not contribute to AMR**, supported by a unique MoA.
  - **Empowering clinicians** to **confidently** and **quickly administer R327** at first patient presentation.
- Use of R327 may **alleviate the selective pressure on bacteria posed by other antibiotics** and allow them to regain efficacy.

Physician perspectives on R327

"We have so few options when patients have difficult pathogens. This agent would be great to come into play for them." – ID KOL

"This may start off being used in resistant patients, but if it is really compelling, of course physicians will use it for more people." – Pulm. KOL

"If a patient has M. abscessus, they're fortunate if they get any improvement, and there's sometimes potentially permanent damage."
– Pulm. KOL

MDR: Multidrug Resistant; ROA: Route of Administration; IV: Intravenous; MOA: Mechanism of Action; KOL: Key Opinion Leaders. Source: Physician Interviews; Clearview Analysis.

Recently Approved Antibiotics – Benchmark for Pricing

Anticipated Pricing Benchmarks[1]

- Though Xigris (activated protein C) was pulled from the market in 2011, its pricing represents a potential premium benchmark for a novel sepsis agent
- Fetroja, a recently approved agent for UTIs, was granted an NTAP by CMS with a maximum payment of ~$8K for a patient treated with the agent
- Arikayce (Amikacin) is an aminoglycoside antibiotic. Used to treat certain kinds of bacterial infections in the lungs, with a potential pricing as low as USD $27K

Physician Perspectives

"A novel molecule demonstrating convincing efficacy may get pricing up to $15 – 20 K like Xigris." – Payer

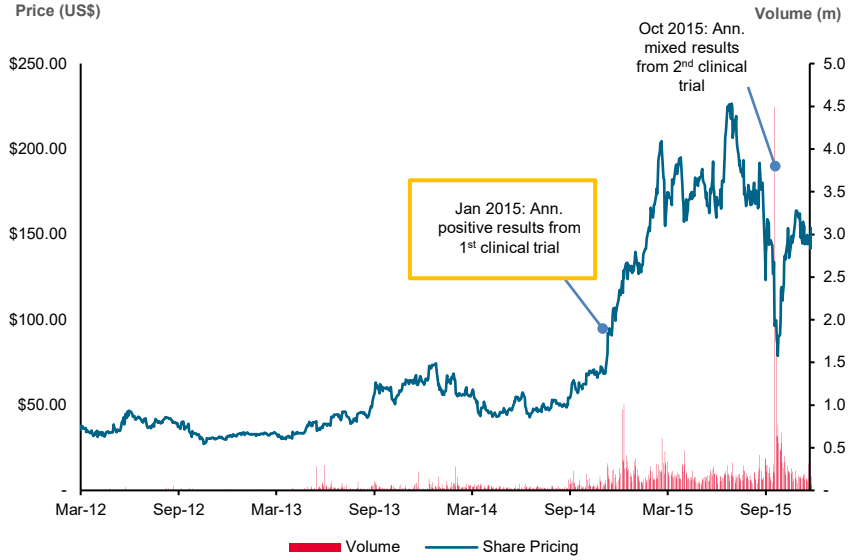
"Cost savings are important here; even if we don't see that many sepsis patients annually, the individual patient cost is very high." – Payer

[1] Antibiotic prices assume an average 7 – 10 day treatment course, although duration of antibiotic therapy in sepsis is not well characterized; [2] DRG codes are differentiated based on whether patient is ventilated for >96 hours and designation of major complications/comorbidities. HEOR: Health Economics and Outcomes Research; NTAP: New Technology Add-on Payment. Source: Busch. The Journal of Infectious Diseases. 2020; Paoli. *Crit Care Med.* 2018; CMS; Payer Interviews; ClearView Analysis.

Successfully Completing a Clinical Trial Phase Can Lead to Significant Share Price Increase

Case studies: Other antibiotic companies

- **Positive top line results** from a global, pivotal Phase III clinical trial of solithromycin oral capsules (Solitaire-Oral) **in the treatment of patients with community acquired bacterial pneumonia.**
- **Solithromycin met the primary and secondary objectives** of non-inferiority compared to moxifloxacin.



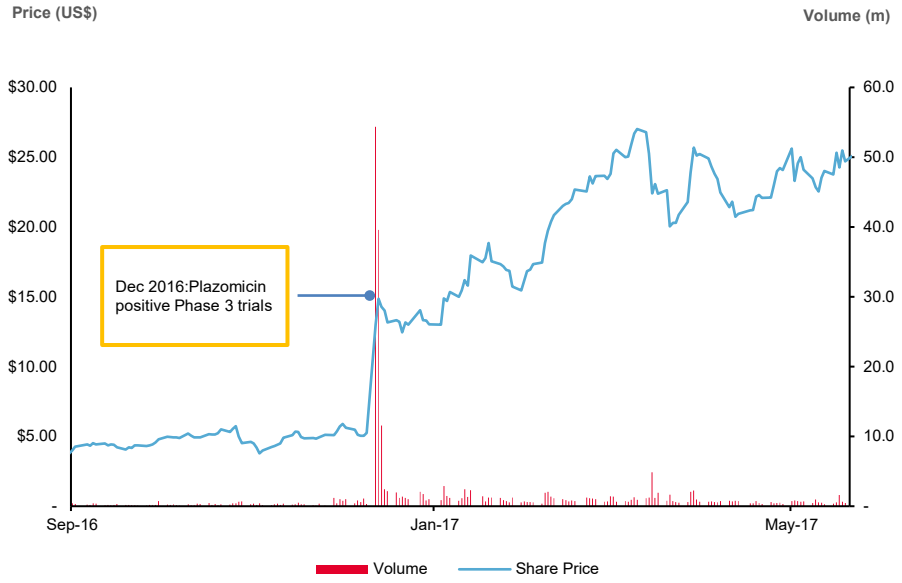
https://www.globenewswire.com/en/news-release/2015/01/04/694774/26624/en/Cempra-Announces-Positive-Topline-Phase-3-Clinical-Results-for-Oral-Solithromycin-in-the-Treatment-of-Community-Acquired-Bacterial-Pneumonia.html

Successfully Completing a Clinical Trial Phase Can Lead to Significant Share Price Increase

Case studies: Other antibiotic companies

ACHAOGEN

- In December 2016, Achaogen announces **positive results in Phase III cUTI and CRE clinical trials of Plazomicin**.
- EPIC registration **trial successfully achieved FDA primary endpoints in patients with cUTI**.
- Achaogen planned to submit a new drug application (NDA), which will include EPIC and CARE data, to FDA in second half of 2017.



https://www.reuters.com/article/idCNASC09MUW

Many recent deals within the anti-infectives space have seen larger companies with an entrenched presence acquiring smaller Biotech's

Key Recent Deals in Infectious Disease

Companies Involved	Deal Details	Total Value	Key Takeaways
Pfizer / amplyx	• **Deal Date:** April 2021 • **Deal Type:** Acquisition of Company	Undisclosed	• Amplyx was developing therapies for patients with compromised immune systems • Antifungal lead compound, Fosmanogepix, in Phase 2 clinical trials
SANDOZ A Novartis Division / gsk	• **Deal Date:** February 2021 • **Deal Type:** Acquisition of Brands	Up to $500 M	• Sandoz acquired GSK's cephalosporin antibiotics business including global rights to Zinnat, Zinacef, and Fortum • $350 M upfront and up to $150 M in milestones
La Jolla Pharmaceutical / TETRAPHASE	• **Deal Date:** July 2020 • **Deal Type:** Acquisition of Company	Up to $75 M	• $43 M upfront and up to $32 M in milestones contingent on net sales of Xerava • Tetraphase terminated previous agreement with Melinta given La Jolla's stronger offer
Roche / FORGE Therapeutics	• **Deal Date:** March 2020 • **Deal Type:** Research Collaboration and Licensing	Up to $190.5 M	• Roche licensed Forge's FG-LpxC LUNG, an antibiotic for treatment of lung infections attributed to antibiotic-resistant Gram-negative bacteria

Source: Global Data; Press Releases; ClearView Analysis