Key Opinion Leader Event

Clinical Data Milestones: The Recce Innovation Journey

ASX:RCE | FSE:R9Q

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Event Agenda

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Recce Pharmaceuticals Ltd

Prof Eugene Athan

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Principle Investigator of Phase II Clinical Trial of R327G
Barwon Health

Dr Alan W Dunton MD

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Phase II RECCE® 327 Topical Gel

Acute Bacterial Skin and Skin Structure Infections

Professor Eugene Athan OAM

MBBS, FRACP (Infec Dis), MPH, MD

Principle Investigator of Phase II Clinical Trial of RECCE® 327 Topical Gel

Introduction

Professor Eugene Athan

MBBS, FRACP (Infec Dis), MPH, MD

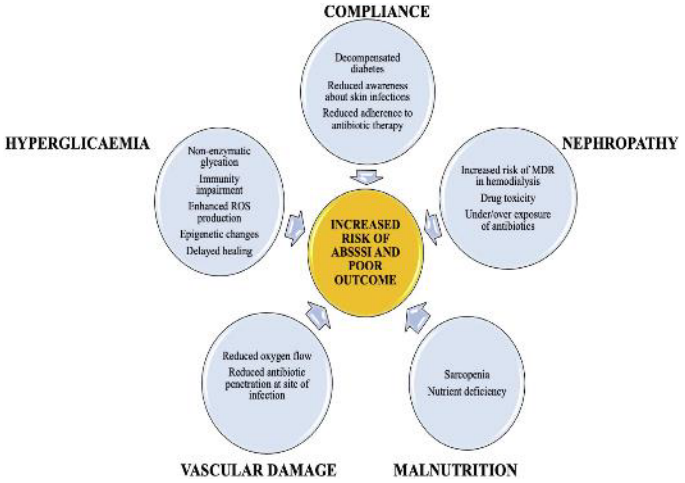
- OAM for service to Infectious Diseases Medicine
- Professor of Medicine, School of Medicine Deakin University
- Co-Director of the Centre for Innovation in Infectious Disease and Immunology Research at Deakin University
- Infectious Disease Specialist at Barwon health
- Director for the Barwon Southwest Public Health Unit, Victorian Government

Professor Eugene Athan
Principle Investigator of RECCE® 327 Topical Gel Clinical Trial

Acute Bacterial Skin and Skin Structure Infections (ABSSSI) and Diabetic Foot Infections (DFIs)

ABSSSI & DFI – Unmet clinical needs

- **Diabetic foot ulcers and infections are common complications that can lead to amputations.**
- **About 50%–60% of ulcers develop infection** which is the leading pathology that devastates most diabetic feet.
- **Readmission rates** for patients with diabetic foot infections **are approximately 40%** and there is almost **a one in six mortality** within 1 year of infection.
- Several pathogens, such as *Staphylococcus aureus*, *Enterococcus*, *Pseudomonas . aeruginosa*, and *Escherichia coli*, typically cause DFI infections, with **50-80% of wounds being polymicrobial.**
- **During the last decades, a significant increase in the prevalence of methicillin-resistant *Staphylococcus aureus* has been detected among hospitalised patients with diabetes with skin infections.**



Several factors affect risk and outcome of ABSSSIs in patients with diabetes mellitus

Current Therapy for Treating DFIs and ABSSSIs

- **ABSSSIs are a significant healthcare concern, encompassing indications such as DFIs, necrotizing fasciitis, and post-operative wound infections.**
- No placebo-controlled studies as international regulators deem it unethical to withhold appropriate treatment of patient infections.
- Wound care, surgery and broad-spectrum antibiotics.

Phase II RECCE® 327 Topical Gel

Clinical Trial Overview

- The Phase II clinical trial is an Open-label, Efficacy Study and Exploratory Evaluation of the Systemic Bioavailability of Single and/or Multiple Doses of R327 Topical Gel Applied to Acute Bacterial Skin and Skin Structure Infections.

- Tested in both men and women with a minimum age of 18 years old and no maximum age limit.

- **The study aimed to provide critical data on the gel's effectiveness in treating a broad range of ABSSSI, including DFIs.**

- Clinical Trial Site – ***Barwon Health***
  - One of the largest and most comprehensive regional health services in Australia
  - Access to a diverse patient population

Phase II ABSSSI Clinical Trial

Achieved all Endpoints

- This Phase II study **achieved all primary and secondary endpoints** as an open-label clinical trial evaluating the safety and tolerability, efficacy, and plasma pharmacokinetics of R327G when applied directly to the infected area
- The study enrolled 30 patients, with 29 included in the final data analysis. One patient was withdrawn due to pre-existing pain at the wound site that was deemed unrelated to R327G
- After 7 days of treatment, 86% of patients (25 out of 29) treated with R327G had a successful clinical response
- At 14 days of treatment, **93% of patients** (27 out of 29) **achieved a primary efficacy endpoint**
- **R327G demonstrated to be safe and well tolerated, achieving all endpoints - no Serious Adverse Events** reported

Study Outcome*	To evaluate the efficacy of RECCE®327 topical gel on ABSSSI
Assessment method	Lipsky Scale/Bates Jensen Wound Assessment Tool
Endpoint met	Yes

*https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=387997&isReview=true

FDA Accepted Diagnosis Tools

Assesses Severity of Patient Wounds

Endpoints

- To evaluate the efficacy of RECCE® 327 topical gel on ABSSSI
- To evaluate the potential for systemic bioavailability of single and multiple doses of RECCE® 327 topical gel applied once daily for 7 or 14 days to infected ABSSSI

DFI: Diabetic Foot Infection Scale (Derived by Lipsky Clinical Resolution of Infection Scale; FDA accepted)

- 7 parameters graded 0-3 for 21 total points (higher the score, worse the DFI)
- Erythema, Exudate (purulent and non-purulent separate), Induration, Tenderness, Pain, Warmth

ABSSI: Bates/Jensen Wound Assessment Tool (FDA Accepted)

- Parameters graded 0-5 for 65 points (higher the score, worse the ABSSI wound)
- Size, Depth, Edges, Undermining, Necrotic Tissue Type and Amount, Exudate type and amount, Skin Colour Surrounding Wound, Tissue Oedema, Tissue Induration, Granulation, Epithelialization

These methods are used to evaluate patient wound healing, and subsequently rated patients as either cured or improved.

Potential of RECCE® 327 Gel for Future Applications

- ✓ ***No Serious Adverse Events demonstrated with R327G***
- ✓ **Results demonstrate the potential of R327G to address the ABSSSI market**
  - – ABSSSIs present a considerable challenge to healthcare system
  - – Those are high risk of skin infections and poor outcomes from ABSSSI are diabetic patients
- ✓ **Rapid onset of effect of R327G** (majority of responses occurred by week 1)
- ✓ **R327G potential in a clinical setting** – robust therapeutic potential

References

- https://www.sciencedirect.com/science/article/pii/S0168822721000851
- https://www1.racgp.org.au/ajgp/2020/may/diabetic-foot-ulcer
- https://pmc.ncbi.nlm.nih.gov/articles/PMC7919962/
- https://jfootankleres.biomedcentral.com/articles/10.1186/s13047-020-00406-y?utm_source=chatgpt.com
- https://pubmed.ncbi.nlm.nih.gov/20146051/

Clinical Overview & Phase 3 Implications

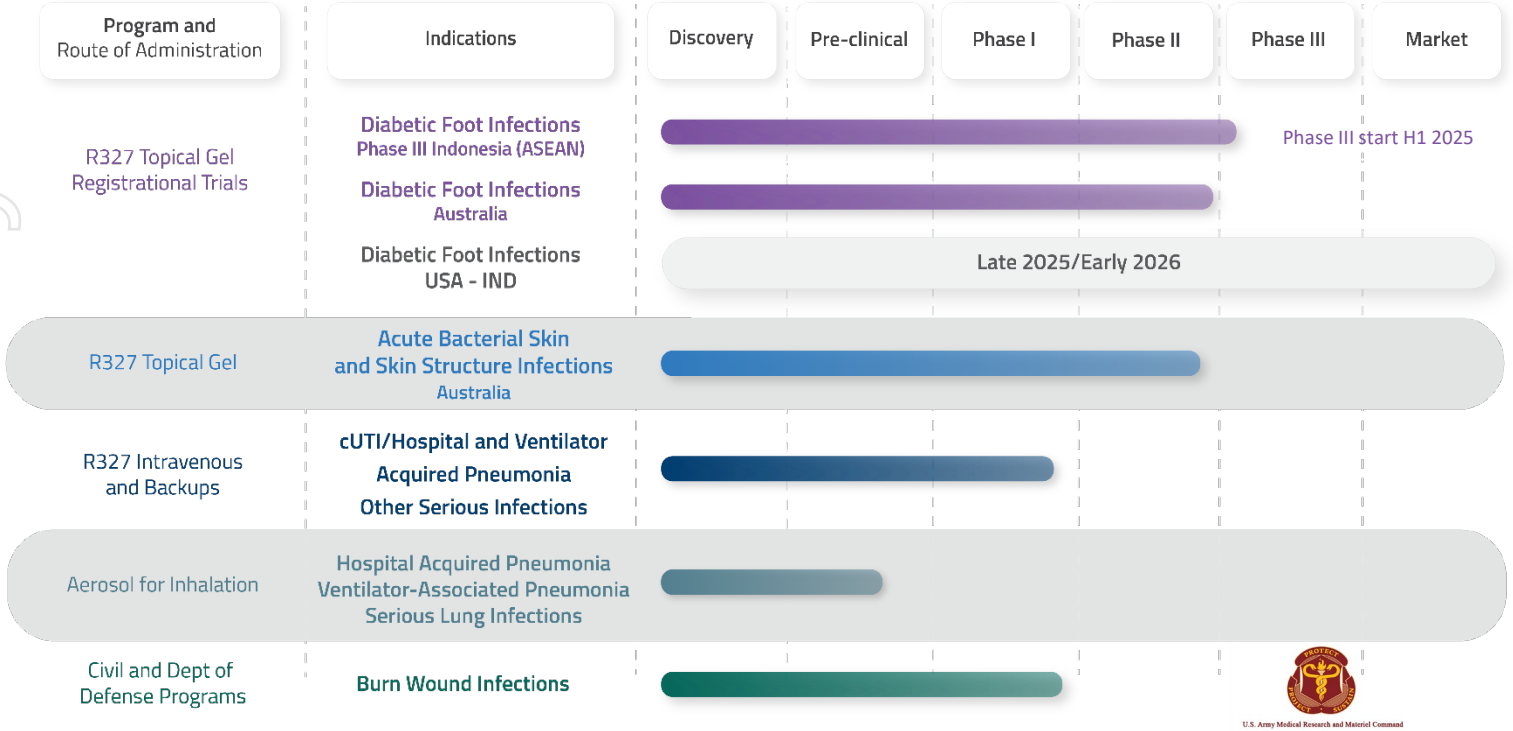
Dr Alan W Dunton *BSc (BioChem) Hons, M.D. (NYU)*

Chief Medical Advisor & Non-Executive Director

Recce Pharmaceuticals

Recce Pharmaceuticals Ltd. Pipeline 2025

Over Various Indications and Upcoming Inflection Points



- Approval received from the Indonesian Drug and Food Regulation Authority, Badan POM, to initiate its Registrational Phase 3 clinical trial in Indonesia
- ABSSSI includes postoperative infection, wound infections and diabetic foot infections
- Completed pilot civil Phase II Burn Wound Infections Study; US$2M grant for Department of Defense pre-clinical pipeline in progress

Phase II ABSSSI Clinical Trial

Study Highlights

- Successful Phase II clinical trial assessing efficacy and safety of once daily RECCE® 327 topical gel (R327G) in patients with Acute Bacterial Skin and Skin Structure Infections (ABSSSI) including patients with Diabetic Foot Infections (DFI)
- **Primary Efficacy Endpoint results: 93% achieved within the 14 day treatment period**
- Phase 3 Studies will utilize same endpoints - Phase II data confirms approach for the Approved Registrational Phase 3 DFI Indonesian Study,
- Trial results continue to reinforce the unprecedented efficacy of Recce's synthetic technology, now in late-stage clinical trials, facilitated by an innovative regulatory strategy, supporting an accelerated commercialisation pathway into 2026

RECCE® 327 Topical Gel: Phase III in DFI

Multicentre Indonesia

- Double blind, Placebo-controlled, Parallel group Study in Patients with DFI
- Drug to be administered once daily for up to 14 days
- N=300 patients (200 active, 100 placebo)
- Primary endpoint is “clinical response” – per standard used by US FDA and other regulatory authorities for this indication and consistent with Phase II study
- **Interim analysis at ~100 patients**
- To be conducted at no more than 10 centers across Indonesia

Diabetic Foot Infection Phase III in Indonesia

Significantly Derisks and Accelerate R327 Gel Clinical Development

- **IND/ Phase III Registrational Clinical Trial approved**
- **Awarded expedited regulatory review status** in Indonesia to fast-track progression of Phase 3 trial
- **Expected launch in 2026 in ASEAN region** – 680 million inhabitant, including 280 million in Indonesia

Recce & Badan POM - Recce CEO James Graham (centre left) and Head of Drug and Food Authority Badan POM, Professor Taruna Ikrar (centre)

Large Addressable Market

The global diabetic foot infection (DFI) and sepsis market is worth in excess of $US9.5 billion

Global Diabetic Foot Infections (DFI) Market

- The DFI treatment market is estimated to be worth ~US$5.2 billion[1]
- Initially targeting Indonesian market valued at ~US$189m where DFI impacts 11% of the population[2]
- Significant near term opportunity for Recce with registrational Phase III trials anticipated to be completed in FY26 paving the way for future revenues
- Indonesian approvals provide access to the broader Asia Pacific market worth ~US$1.0 billion per year[3]

US$5.2B

Global DFI treatment market[1]

Source: (1) Grand View Research, Diabetic Foot Ulcer Treatment Market Size, 2023 (2) Diabetes Atlas, International Diabetic Federation and Prof EM Yunir, Faculty of Medicines, University of Indonesia. (3) Business Market Insights, Asia Pacific Diabetic Foot Ulcer Market, 2021 (4) ResearchandMarkets, Global Sepsis Therapeutics, 2024 (5) Grand View Research, Anti-Infective Agents Market Size, 2023

Insights from Dr Yukiko Nakatani

WHO Assistant Director-General for Antimicrobial Resistance on the State of Antibacterial Development

June 14, 2024

"**Antimicrobial resistance is only getting worse yet we're not developing new trailblazing products fast enough** to combat the most dangerous and deadly bacteria."

"**Innovation is badly lacking yet**, even when new products are authorized, **access is a serious challenge**. Antibacterial agents are simply not reaching the patients who desperately need them, in countries of all income levels."

Of the 32 antibiotics under development to address 2024 WHO bacterial priority pathogen list (BPPL), only 12 can be considered innovative. Furthermore, **just 4 of these 12 are active against at least 1 WHO 'critical' pathogen** – critical being the BPPL's top risk category, over 'high' and 'medium' priority.

Looking at newly approved antibacterials, since 1 July 2017, **13 new antibiotics have obtained marketing authorization but only 2 represent a new chemical class** and can be termed innovative, underscoring the scientific and technical challenge in discovering novel antibacterials that are both effective against bacteria and safe for humans.

Full report here

WHO Global Priority Pathogens List

Antibiotic-Resistant Bacteria (2024)

Priority 1 - CRITICAL

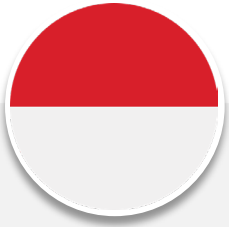
Carbapenem-resistant: *K. pneumoniae* & *A. baumannii*

- **Carbapenem-resistant organisms** are commonly resistant to all beta-lactam antibiotics including the broad-spectrum carbapenem drugs: **meropenem, imipenem, ertapenem, and doripenem.**
- **Carbapenems** are considered the **last line of defense** in treating **multidrug-resistant bacterial infections**.
- **Carbapenem-resistant *Klebsiella pneumoniae* now present in 16 countries and territories**[1]
- **Carbapenem-resistant *Acinetobacter baumannii* identified in 47 countries across Africa, Asia, Europe, Latin America and North America.**[2]

Beta-lactams include: penicillin, cephalosporins, monobactams, and carbapenems

[1] *Antimicrobial Resistance, Hypervirulent Klebsiella pneumoniae - Global situation (WHO 2024)*
[1] *Risk Assessment: Emergence of hypervirulent Klebsiella pneumoniae ST23 carrying carbapenemase genes in EU/EEA countries - first update Feb 2024*
[2] A global view on carbapenem-resistant Acinetobacter baumannii. mBio 14(6) 2023

Global Regulatory Strategy



Expansion into ASEAN

- **Phase 3 ready,** aiming to complete recruitment by end 2025 and read-out in early 2026 with **expected approval in early 2026** (agreed accelerated approval)
- Indonesian approval will facilitate regulatory approval for R327 Gel across broader ASEAN region
  - Countries including Malaysia, Philippines, Singapore and Thailand as a treatment for DFIs

Ongoing IND Preparations

Lung Study data

Dr Sohinee Sarkar *BSc (Biotech), Adv Masters(Biotech), PhD*

Senior Postdoctoral Fellow

Infection, Immunity & Global Health (Respiratory)

Murdoch Children's Research Institute

Recce is at the forefront of tackling antimicrobial resistance

Focus on non-tuberculous mycobacteria (NTM)

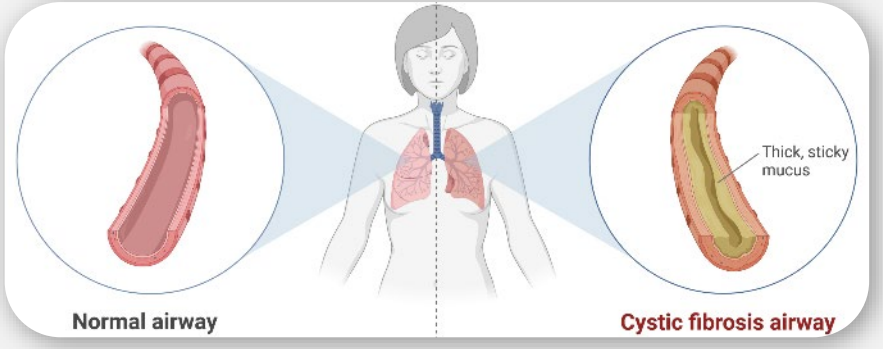
- **NTM comprise mycobacterial spp. other than those causing tuberculosis & leprosy**
- **Opportunistic pathogens increasing in global prevalence**
  - Increasing incidence of NTM in conflict zones due to infected combat wounds
- **NTMs cause a wide spectrum of disease:**
  - TB-like lung disease
  - Localised infections (soft tissue)
  - Systemic infections
- **High risk populations:**
  - Chronic lung disease: emphysema, asthma, COPD, bronchiectasis, cystic fibrosis
  - Immunosuppression (chemotherapy, HIV, long term steroid use, renal failure, transplant recipients)
  - Older people
- **Highly drug resistant; treatment failure rates can be >50% for some NTM spp.**

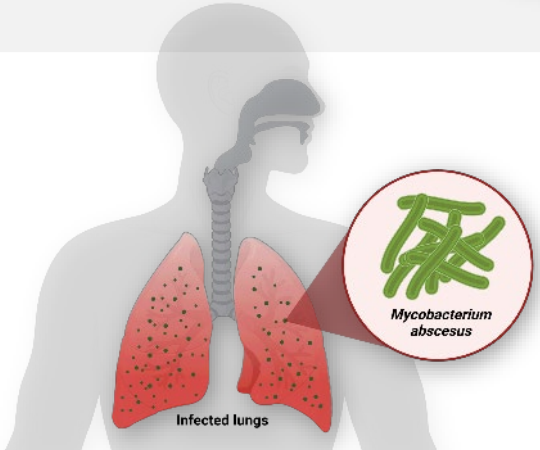
Mycobacterium abscessus (M. abscessus):

A Cystic fibrosis superbug

Background

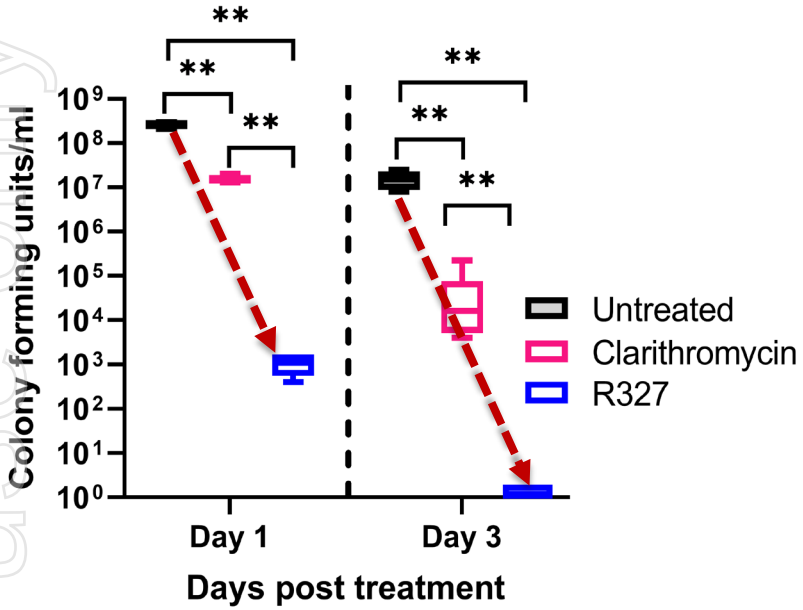
- Cystic fibrosis is an inherited disorder; defect in the *CFTR* gene (chloride channel)
- Multi-organ disease affecting primarily the lungs & digestive system
- Lungs: repeated infections and resulting inflammation leading to lung damage





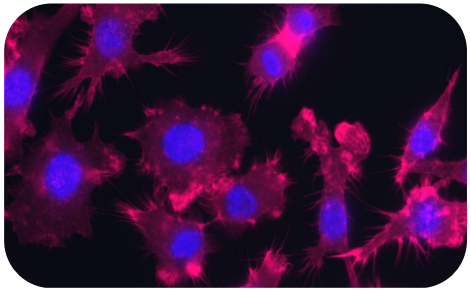
- *M. abscessus:* an important CF pathogen (3%-20%) - **extremely difficult to treat & can accelerate lung damage**
- Current treatment plans involve cocktails of antibiotics (Rx can last 1-2 years, high toxicities, **high failure rates often up to ~50%)**

Preclinical validation of R327 against *M. abscessus*

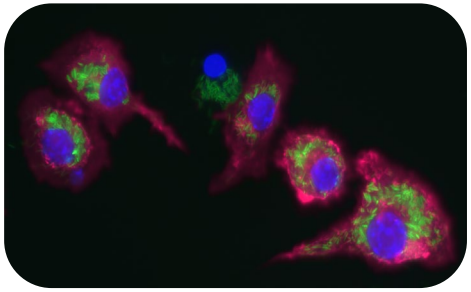


- ✓ R327 outperforms clarithromycin
- ✓ No host cell cytotoxicity detected

Uninfected macrophages



Infected macrophages



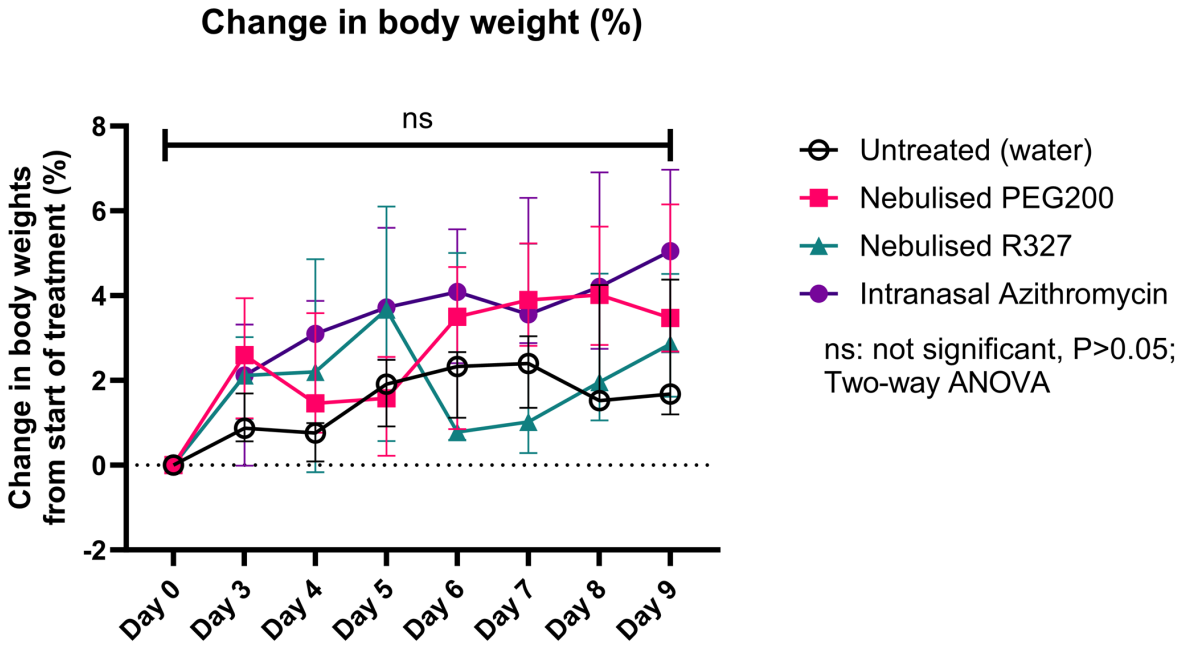
Nebulised Delivery of R327

Against M. abscessus lung infection

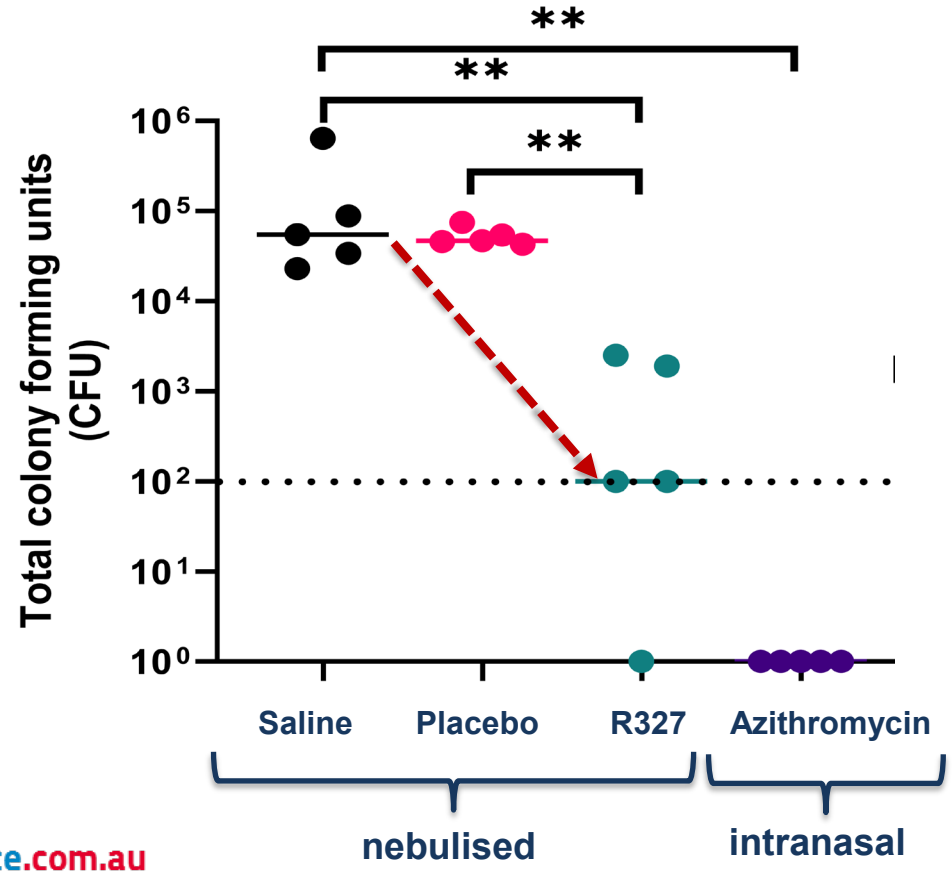
TNF-α deficient mice

R327 Delivery to the Lungs is Safely Tolerated

With no adverse effects in mouse lung infection model



Nebulised R327 retains its efficacy in the mouse lung



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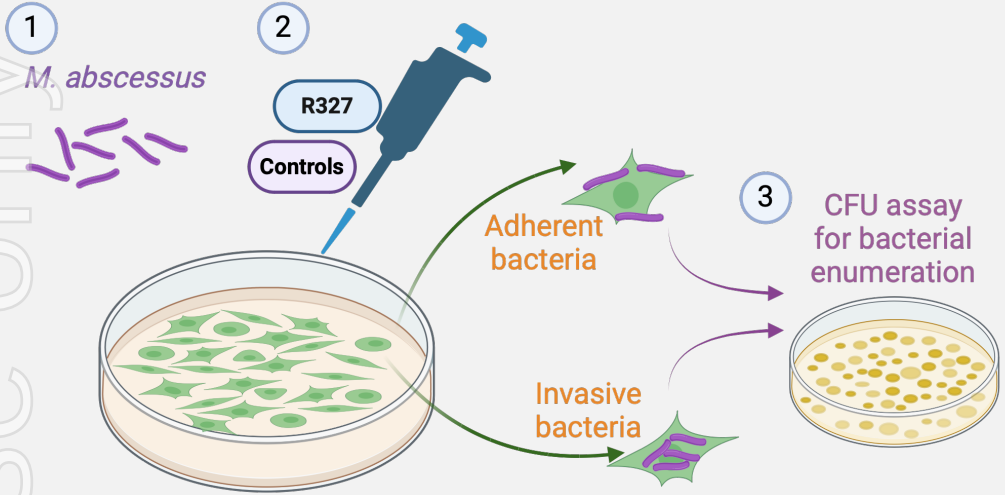
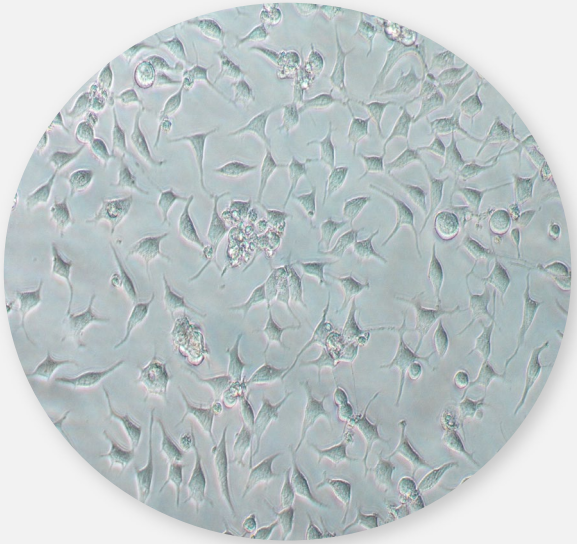
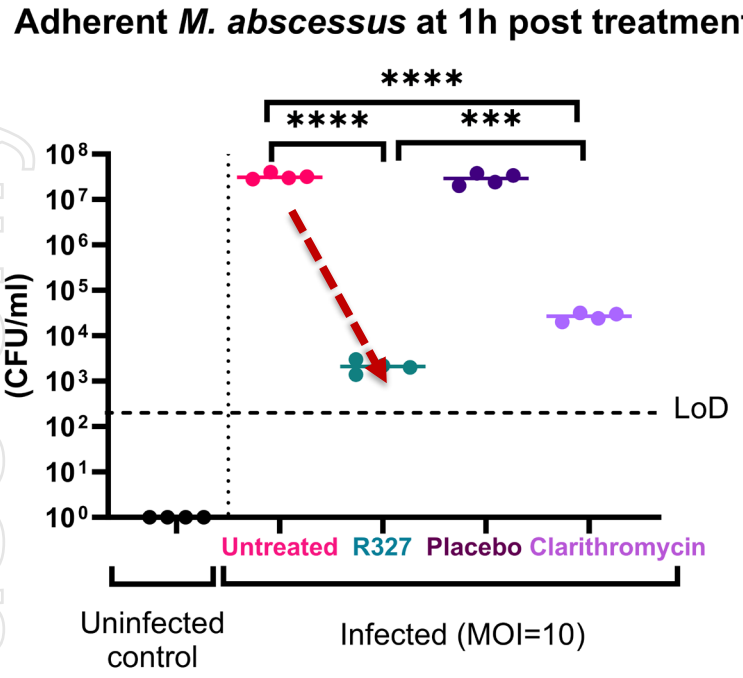
R327 efficacy against *M. abscessus* skin infection

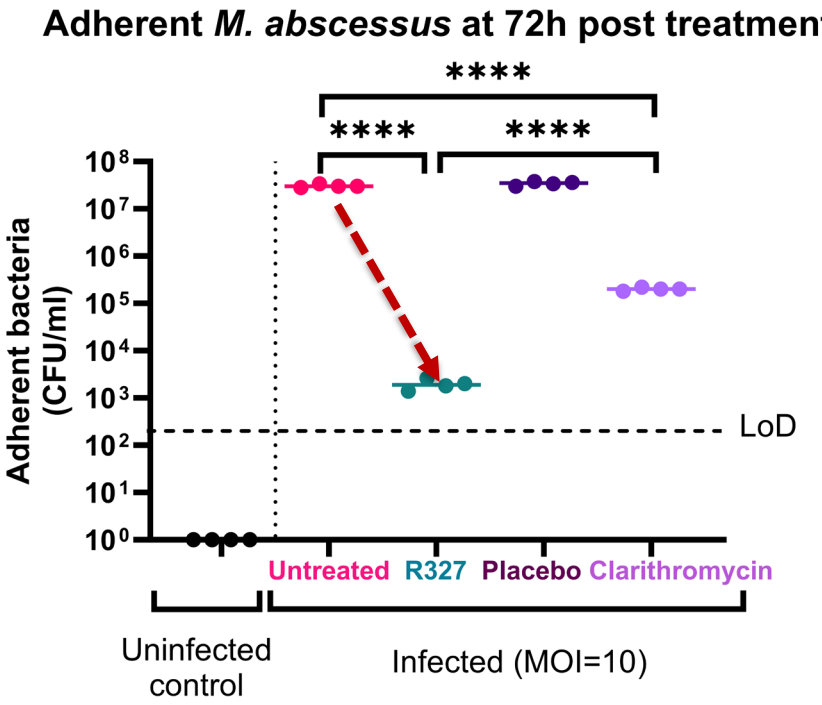


Keratinocyte cell line

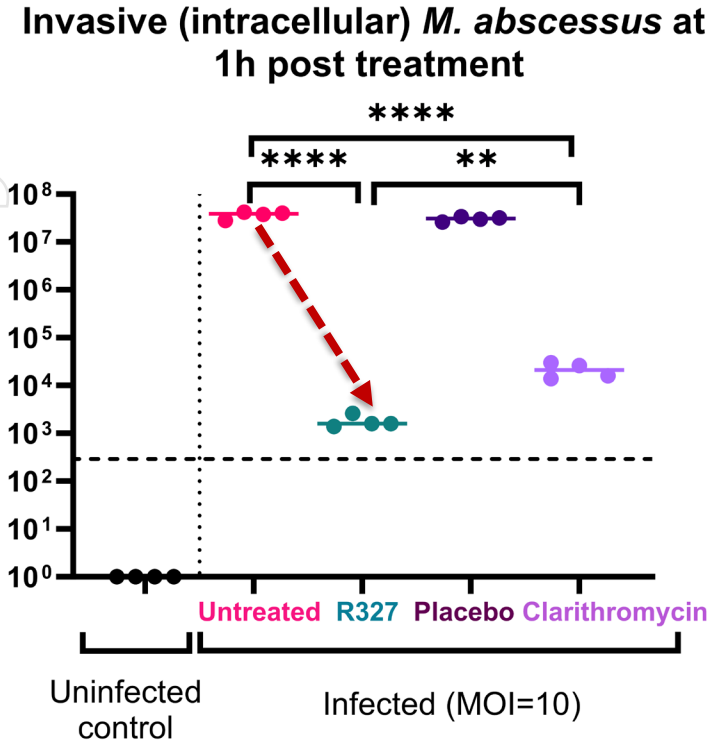


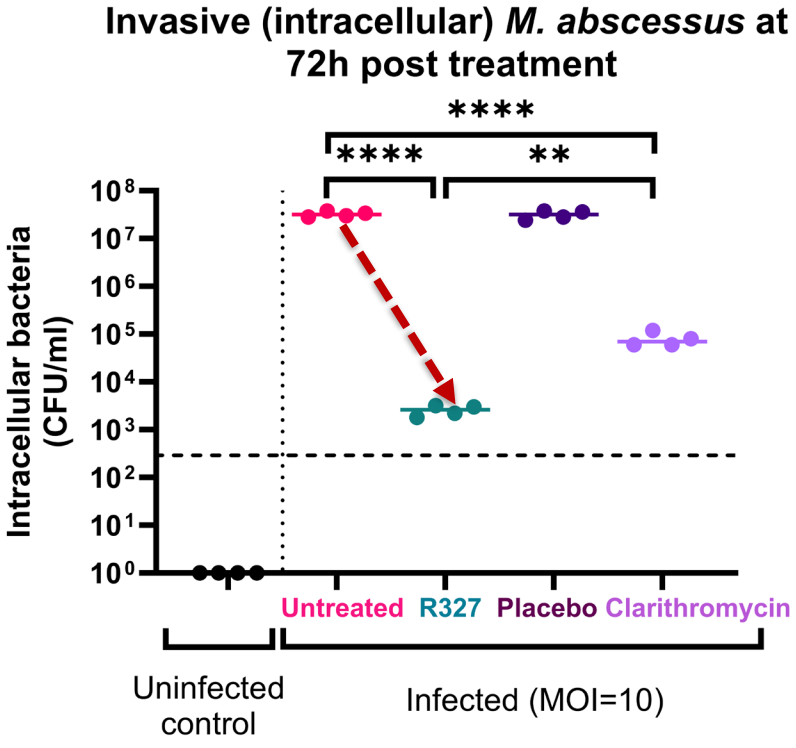
R327 efficacy against *M. abscessus* skin infection





R327 efficacy against *M. abscessus* skin infection





R327: A Promising Candidate For Treating NTM Infections

Nontuberculous mycobacteria (NTM) cause a wide spectrum of infections ranging from skin/soft tissue infections to tuberculosis-like lung disease

- **R327 shows promising efficacy against both lung and skin infections caused by *M. abscessus***, one of the most common and highly-resistant NTM species
- **Lung study data demonstrates impact in respiratory function**, providing new hope for addressing anti-infective challenges.
- **Nebulised R327 can be safely delivered while retaining its efficacy**
- Current NTM therapeutics are associated with long treatment times, significant adverse effects and high treatment failure rates. **R327 presents a viable alternative as a safe and effective treatment option to improve patient outcomes.**

Company Update

James Graham

Managing Director & Chief Executive Officer

Recce Pharmaceuticals

Recce Pharmaceuticals – Company Overview

An Australian clinical-stage biotech with a United States presence, developing a New Class of Synthetic Anti-infectives with a unique mechanism of action for a broad spectrum of infections including serious/life-threatening indications.

- Publicly-traded on the **Australian and Frankfurt exchanges – (ASX: RCE, FSE: R9Q)**
- **>40 granted patents** across major pharmaceutical markets out to 2041
- Phase II Clinical trial (complete, Australia); Phase III Clinical trial ready (Indonesia).
- Additional Phase III studies will be conducted primarily in Australia.
- **United States Congressionally Directed Medical Research Program (CDMRP) for Military Burn Research Program – in progress**
- **Our Goal is regulatory approval and commercialisation of products globally.**

RECCE® 327 granted Qualified Infectious Disease Product (QIDP) Designation by U.S. Food and Drug Administration giving 10 years market exclusivity plus fast-track approval.

RECCE® 327 added to World Health Organization's List of Antibacterial Products in Clinical Development

Recce Products are *Dramatically Differentiated*

Unprecedented, **broad-spectrum activity against Gram +ve and Gram -ve bacteria**, **tested against over 400 clinical strains**

Novel Universal Mechanism of Action

Extremely rapid onset of effect – measured in minutes as compared to hours for typical antibiotics

Are ALL Synthetic, not derived from nature – **with NO signs of resistance**

Selective activity against prokaryotic cells and not against eukaryotic cells

Multiple formulations – intravenous solution (can be used topically or as an intranasal spray), and topical gel aerosol for inhalation (in development)

On-track to be the only **global clinical stage company** whose drug is shown to be **efficacious** against the full suite of **ESKAPE pathogens.**

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	**Allowed**	2041
China	✓	2028	✓	2037	✓	2037	Pending	-
HK	Pending	2028	Pending	2037	✓	2037	Pending	-
Israel	-	-	-	-	-	-	✓	2041
Canada	-	-	-	-	-	-	✓	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/granted)

Significant Value Creation Potential

- **Novel, Synthetic, Broad-Spectrum, Rapid-Acting, Anti-Infectives: demonstrated against >400 clinical isolates;** ***no signs of resistance***
- **Highly successful Phase 2 with Phase 3 clinical trial approved to begin for ASEAN;** Australia and beyond expected to follow
- **>40 granted patents** across major pharmaceutical markets out to 2041
- **Significant manufacturing economies/low cost of goods** and scalability
- **R327 uniquely classified by World Health Organization as the only compound under ATP production disruptor category**
- Development of a **first new class of antibiotic in over 40 years; with accelerated de-risking** through Recce's innovative regulatory pathway and market entry
- *Recognised by* ***US FDA with QIDP*** *designation and* ***US DoD (Army) – Approved Grant,*** *Work in Progress*

Thank you