ASX Announcement

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Positive Data for RECCE® 327 in MRSA Burns Wound Infection

- **RECCE® 327 antibiotic shows significant efficacy against MRSA (superbug) in treatment of burns wound infection in an animal model**
- **Wound contraction (healing) - greater than market drug**
- **Human clinical irritation test - no observable irritation after 24 hour application**
- **Data will be used in support of a hospital ethics submission for patient study**

SYDNEY Australia, 27 November 2019: Recce Pharmaceuticals Ltd (ASX: RCE) (**Company**), the company developing a new class of antibiotics reports positive data in a rat topical burns model from an assessment of its lead compound RECCE® 327 in addressing the unmet medical needs of burns treatment and associated difficulties in wound closure.

The study was undertaken in co-operation with an established Australian teaching hospital, by an independent Contract Research Organisation (CRO). Top line results showed significant *in vivo* antibacterial activity against Methicillin-Resistant *Staphylococcus aureus* (MRSA – superbug) in rats with topical burns: RECCE® 327 reduced bacterial load and enhanced wound closure. A separate human skin model showed the antibiotic was non-irritating, even at high concentrations.

The data from this study will be presented to the ethics committee at a hospital in Australia, with the intention of utilisation on patients in-need, including optimising data collection for regulatory advancement.

Recce Chairman Dr. John Prendergast said: “These data demonstrate that RECCE® antibiotics has great potential to be applied in a broad range of clinical treatment settings. With significant data synergies from our lead indication in the treatment of sepsis, to another area of urgent unmet need, these new results support Recce’s potential to address the increasing threat of antibiotic resistant superbugs”.

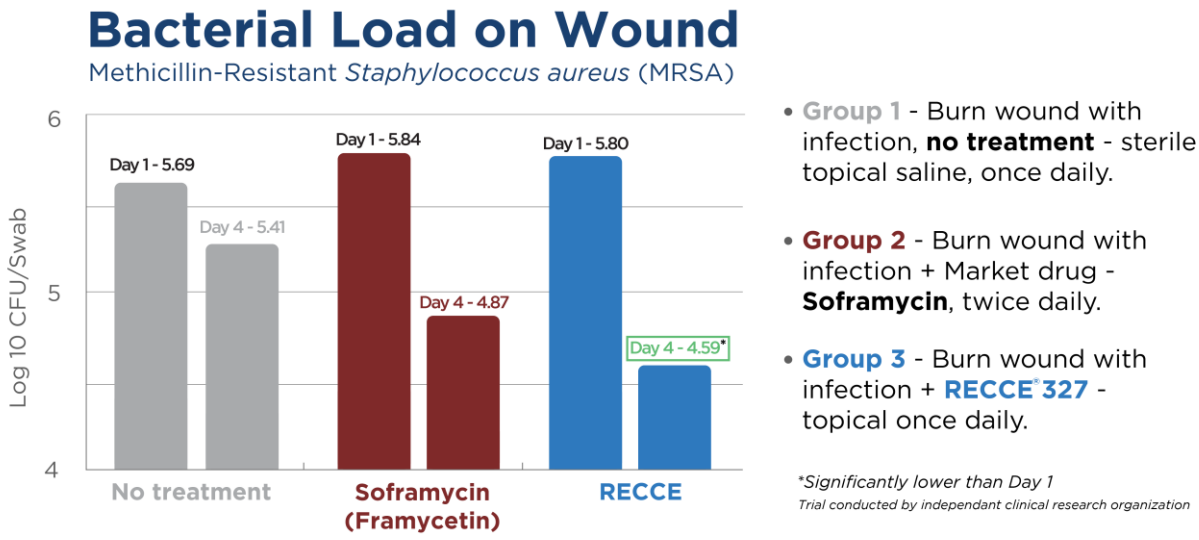
Methicillin-Resistant *Staphylococcus aureus* (MRSA) is a leading cause of wound infections globally, with United States reporting 327,700 cases of MRSA in hospitalised patients and 10,600 estimated deaths in 2017 – attributing US $1.7 billion (AU$2.5 billion) to healthcare costs[2].

RECCE® 327 was previously awarded Qualified Infectious Disease Product (QIDP) designation by the US Food and Drug Administration as a broad-spectrum antibiotic for intravenous (I.V.) indication against bacteraemia (sepsis, derived from *E. Coli & S. aureus).* Grant of patents has extended claims as an 'antibiotic technology' with multiple forms of administration.

Detailed data

1. **Bacterial load assessment**

Three groups of five Rats, showed RECCE® 327 performed better than both the positive and negative controls, with statistically significant reduction in bacterial load in the infected wound.



	Log_{10} CFU/Swab (Mean)		
Group	Treatment	Day 1 PI**	Day 4 PI**
1	Burn wound With infection	5.69	5.41
2	Burn wound With infection + Reference Standard (Soframycin***)	5.84	4.87
3	Burn wound With infection+ RECCE® 327 Test Dose	5.80	4.59*

* Significantly lower than day 1 ($p<0.05$, paired t test)

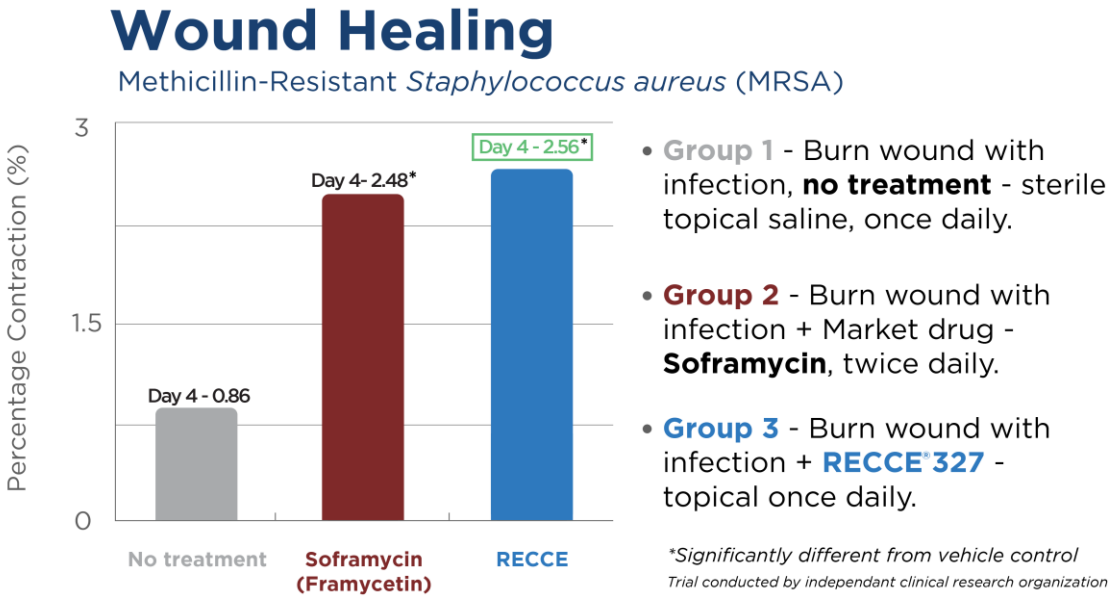
**PI – Post Infection

*** Topically marketed antibiotic for the treatment of bacterial infections in burns and wounds[1]

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."*

2. **Wound contraction assessment (healing)**

The CRO further assessed RECCE® 327 Wound Contraction (healing of the wound).



Group	Treatment	% wound contraction on Day 4 PI**
1	Burn wound With infection	0.86 ± 0.22
2	Burn wound With infection + Market Drug (Soframycin***)	2.48 ± 0.30*
3	Burn wound With infection+ RECCE® 327	2.56 ± 0.47*

* Significantly different from vehicle control (p<0.05, 1 way ANOVA)

** PI – Post Infection

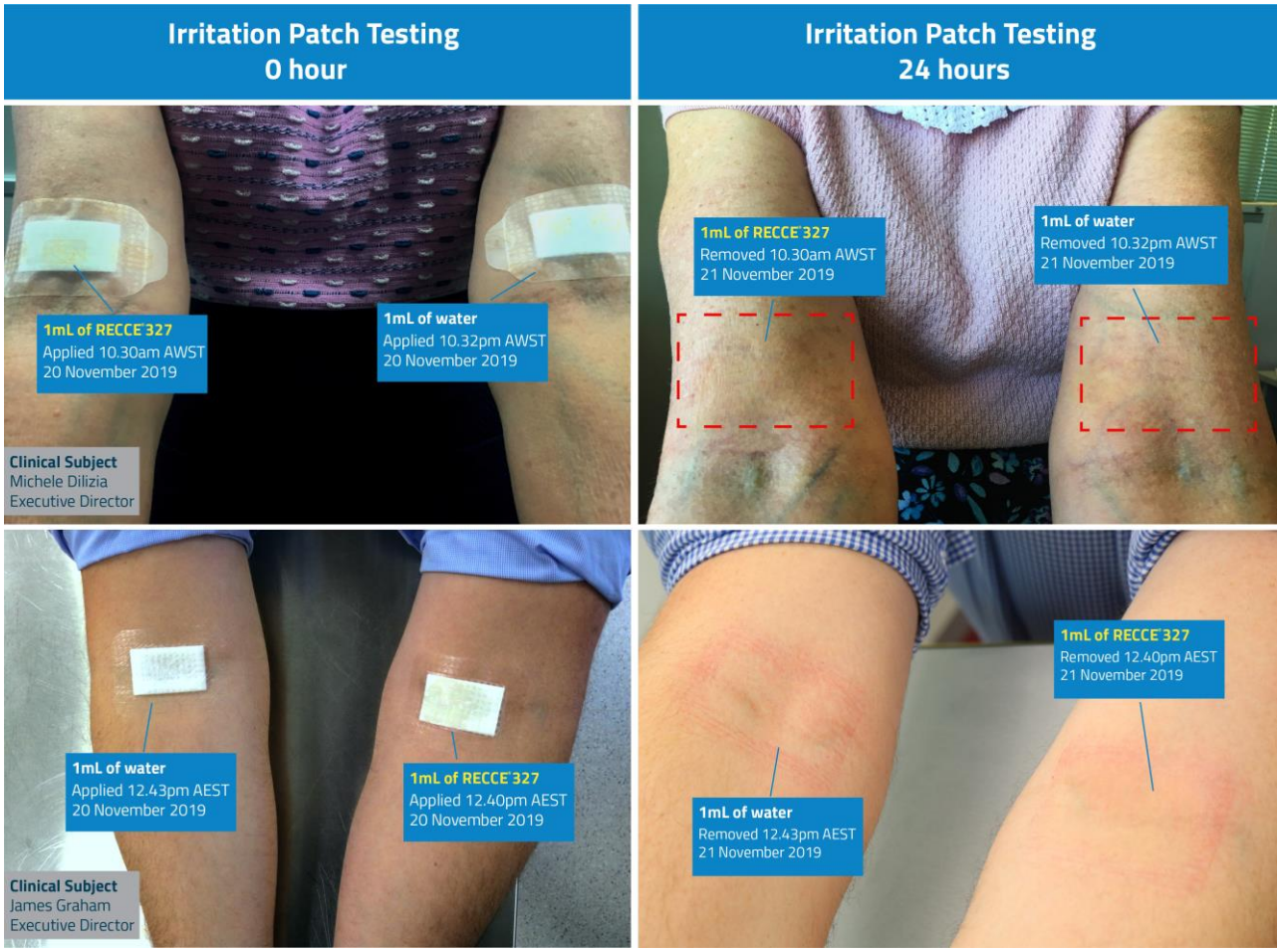
*** Marketed topical antibiotic for the treatment of bacterial infections in burns and wounds[1]

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."*

Dr Graham Melrose, (Executive Director & Chief Research Officer) further noted: *"**RECCE® 327 outperformed the positive control with half the repeated doses and in a diluted form**. This suggests with less dilution/additional application even further efficacy and healing may be observed."*

3. Human clinical skin irritation test

The Company further undertook an informal, but indicative, 24-hour Human Clinical Skin Irritation test on a healthy male and female subject. A recognised irritation study protocol was followed with the support of qualified internal technicians, which saw each subject topically apply undiluted RECCE® 327 on one arm and water on the other arm as the negative control.



At a significantly higher concentration of RECCE® 327 (neat), applied to a sensitive area of their skin, there was **no evidence of discomfort or irritation**, beyond that of the topical adhesive (normal).

1 – Sanofi Drug Information: Soframycin Skin Cream

2 – Centre for Disease Control and Prevention: Antibiotic Resistance Threats in the United States 2019

About Recce Pharmaceuticals

Recce Pharmaceuticals Ltd (ASX: RCE) is pioneering the development and commercialisation of a New Class of Synthetic Antibiotics with Broad Spectrum activity designed to address the urgent global health problem of antibiotic resistant superbugs. Recce antibiotics are unique – their potency does not diminish even with repeated use, which is a common failure associated with existing antibiotic use and the resulting emergence of resistant superbugs. Patented lead candidate RECCE® 327, wholly owned and manufactured in Australia, has been developed for the treatment of blood infections and sepsis derived from *E. coli* and *S. aureus* bacteria – including their superbug forms. The FDA has awarded RECCE® 327 Qualified Infectious Disease Product designation under the Generating Antibiotic Initiatives Now (GAIN) Act – labelling it for Fast Track Designation, plus 10 years of market exclusivity post approval. Recce wholly owns its automated manufacturing, ready to support first-in-human clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of RECCE® technologies targeting synergistic, unmet medical needs.

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