Recce Pharmaceuticals
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ACN 124 849 065

Further Positive Data on RECCE® 327 Against MRSA Superbug in Burn Wound Animal Model

Highlights:

- **Statistically significant reduction in MRSA superbug bacterial load and higher percentage of wound contraction with RECCE® 327 as compared to Soframycin in rat model for topical burns**
- **Study reinforces the potential of RECCE® 327 against drug-resistant superbugs**

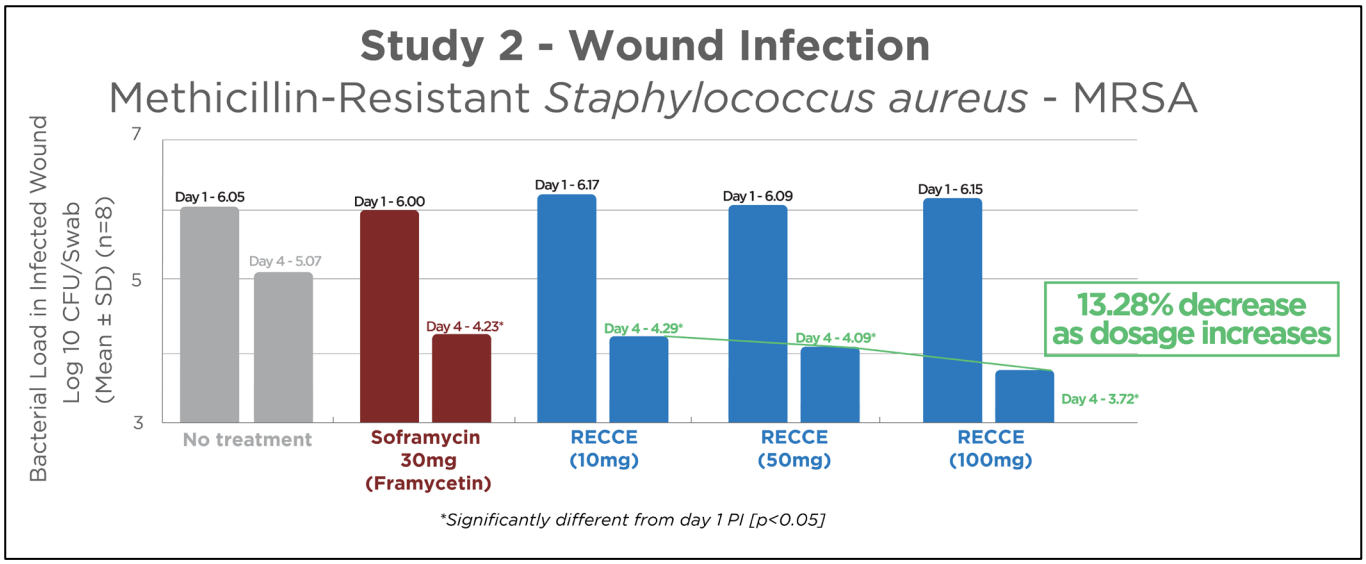
Sydney Australia, 23 April 2020: Recce Pharmaceuticals Ltd (**ASX: RCE**) (**Company**), the Company developing a New Class of Broad-Spectrum Synthetic antibiotics, today announced positive data showing significant *in-vivo* antibacterial activity against Methicillin-Resistant *Staphylococcus aureus* (MRSA superbug) in rats with topical burns treated with its lead compound RECCE® 327.

The study was conducted by an independent Contract Research Organisation to assess the dose-dependency of RECCE® 327 and *in-vivo* antibacterial activity against MRSA in rats with topical burns. It met its primary endpoints which were a reduction in bacterial load in wound and percentage of wound contraction, evaluated on the fourth day following dosing.

RECCE® 327 was effective in reducing bacterial load within a wound and showed enhanced wound contraction in comparison to the best in class - Soframycin. RECCE® 327 showed repeated efficacy at different dosing levels on topical skin conditions even at low doses. This additional antibacterial efficacy data will be presented to a leading Australian teaching hospital for their anticipated clinical trial considerations.

Bacterial Count Assessment

Five groups of eight rats each showed RECCE® 327 performed better in all instances compared to those who received the optimum dose Soframycin treatment or no treatment. RECCE® 327 continued to show efficacy at different dose levels with significant reduction in bacterial count in the infected wound when compared to the vehicle control ($p<0.05$). As dosage increased from 10mg to 100mg, there was a further 13.28% decrease in bacterial load.



	Log_{10} CFU/Swab (Mean ± SD)(n=8)			
Group	Treatment	Day 1 PI**	Day 4 PI**	% Change
1	Burn wound With infection	6.05	5.07	16.2%
2	Burn wound With infection + **Marketed Drug** [30mg] (**Soframycin*****)	6.00	4.23*	29.5%
3	Burn wound With infection+ **RECCE** [10 mg]	6.17	4.29*	**30.5%**
4	Burn wound With infection+ **RECCE** [50 mg]	6.09	4.08*	**33.0%**
5	Burn wound With infection+ **RECCE** [100 mg]	6.15	3.72*	**39.5%**

*significantly different from day 1 PI [p<0.05]
** PI – Post Infection
*** Topically marketed antibiotic for the treatment of bacterial infections in burns and wounds

RECCE® 327 showed a significant dose-dependent antibacterial effect when compared to the vehicle control ($p<0.05$). In this study Soframycin applied twice daily at optimum therapeutic dose whereas a once daily application of RECCE® 327 demonstrated antibacterial efficacy reinforcing RECCE® 327 may be a more potent antibiotic without additional toxicity considerations associated with similar doses of Soframycin.

Wound Contraction/Healing Assessment

RECCE® 327 was further assessed in a wound contraction study. RECCE® 327 showed significant dose-dependent wound healing activity when compared to the vehicle control ($p<0.05$). Additionally, RECCE® 327 was 180% more effective in wound healing as the dose escalated in comparison to the group that received no treatment.

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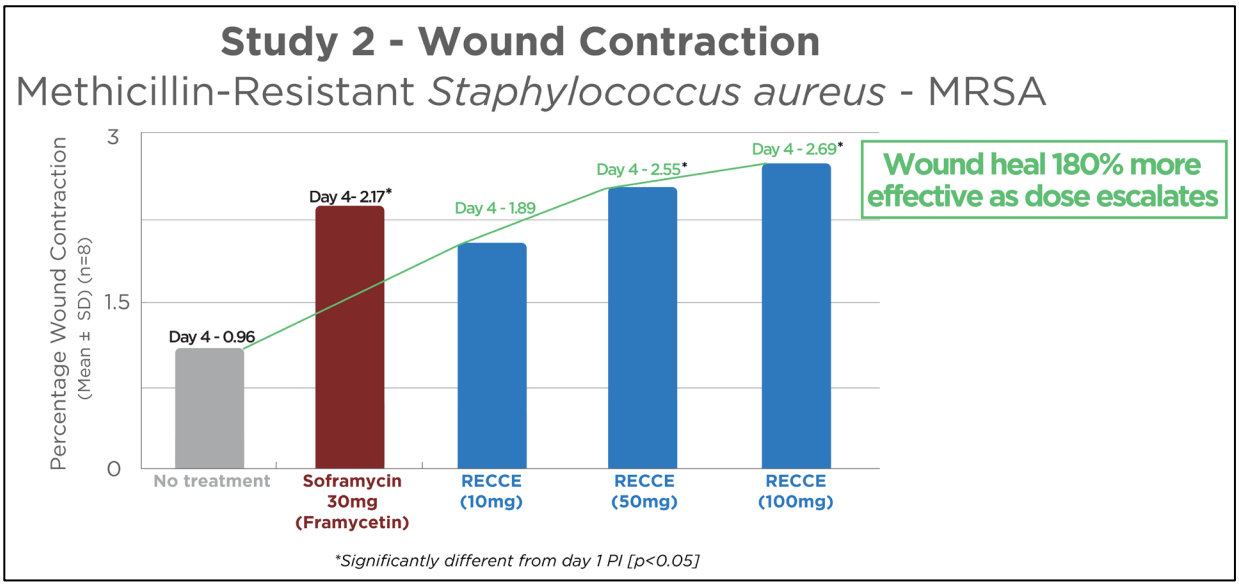

	Percentage wound contraction (Mean ± SD)(n=8)	
Group	Treatment	Day 4 PI
1	Burn wound With infection	0.96 ± 0.54
2	Burn wound With infection + **Market Drug** [30 mg] (**Soframycin**)	2.17 ± 0.81*
3	Burn wound With infection+ **RECCE** [10 mg]	1.89 ± 0.94ns
4	Burn wound With infection+ **RECCE** [50 mg]	2.55 ± 0.49*
5	Burn wound With infection+ **RECCE** [100 mg]	2.69 ± 1.05*

ns Not significantly different from day 1 PI [p>0.05].
* Significantly different from day 1 PI [p<0.05].

Staphylococcus aureus (S. aureus) is a Gram-positive bacteria found on the skin and mucous membranes. *S. aureus* is the most dangerous of all of the many common staphylococcal bacteria. This bacteria often causes skin infections; however, it can also cause pneumonia, bone infections, meningitis and other invasive infections.[1] Patients with MRSA have significantly longer hospital stays and are estimated to be 64% more likely to die than people with a non-resistant form of the infection.[2]

"We are greatly encouraged by the data because it further reinforces RECCE® 327 is potent and keeps on working with repeated efficacy against topical pathogens and superbugs at different dosing levels," said Dr John Prendergast, Non-Executive Chairman. "Recce's synthetic antibiotic out-performed the best in class antibiotic Soframycin showing it could be a potential alternative treatment for resistant *Staphylococcus aureus,* one of the most common bacterial infections in humans."

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

[1] https://www.ncbi.nlm.nih.gov/books/NBK441868/
[2] https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance

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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE) is pioneering the development and commercialisation of a New Class of Synthetic Antibiotics with Broad Spectrum activity designed to address the urgent global health problem of antibiotic resistant superbugs.

Recce antibiotics are unique – their potency does not diminish even with repeated use, 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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