ASX Announcement

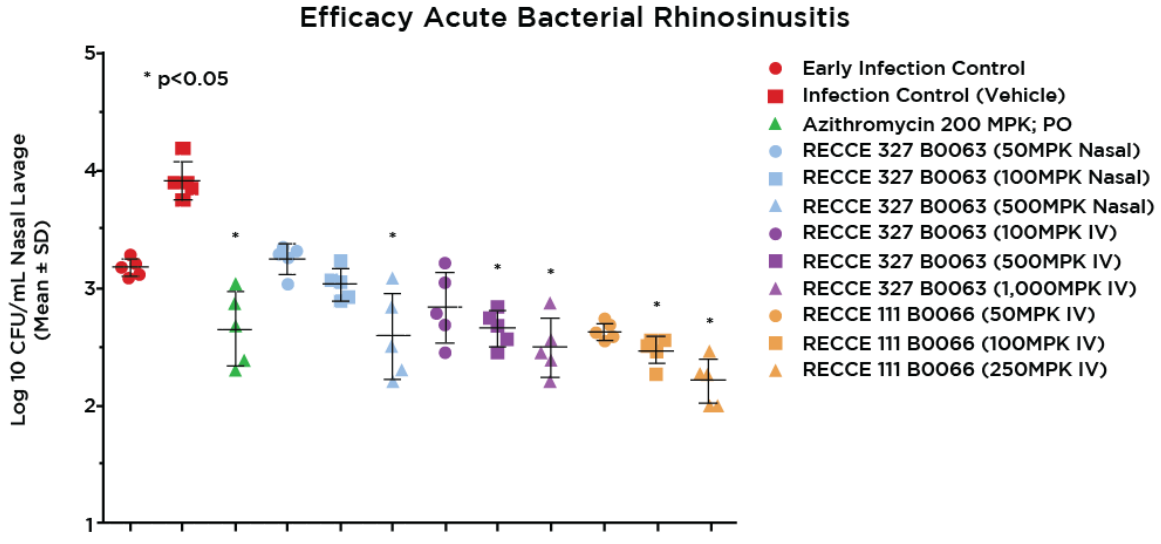
Positive Sinusitis Data Against Infection

Highlights:

- **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**
- **RECCE® 327 (R327) and experimental RECCE® 111 (R111) tested against marketed therapeutic alternative *in-vivo* in sinusitis study; independent study agreement anticipated**

Sydney Australia, 1 April 2021: Recce Pharmaceuticals Ltd (**ASX:RCE, FSE:R9Q**) (**Company**), the Company developing New Classes of Synthetic Anti-Infectives, is pleased to announce animal study data showing positive efficacy of a new anti-infective formulation RECCE® 111 (R111) against *Streptococcus pneumoniae* (*S. pneumoniae)* bacterial sinusitis in mice. RECCE® 111 is a non-descript title for an experimental compound, developed in-house, building upon the unique Mechanisms of Action of RECCE® 327.

The study was conducted by an independent Contract Research Organisation, to assess the dose-dependency of R327 and R111[1] *in-vivo* antibacterial activity against *S. pneumoniae* in a mouse model of acute bacterial rhinosinusitis infection.



[1] 'R111' a non-descript placeholder name for present purposes

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® 111 (Low dose, IV, 50mg/kg, Twice daily, 5 days)	NAD
11	RECCE® 111 (Mid dose, IV, 100 mg/kg, Twice daily, 5 days)	NAD
12	RECCE® 111 (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. *Streptococcus pneumoniae*, a Gram-positive bacterium, is a leading cause of bacterial pneumonia and meningitis in the United States, and a common cause of bloodstream infections, also known as sepsis, ear and sinus infections.[2]

A total of 12 groups of 10 mice each were assessed to determine the effectiveness of R327 and R111 against *S. pneumoniae*. Three groups were treated with varying intranasal doses twice daily of R327 (50, 100, 500 mg/kg) and showed a significant dose-dependent antibacterial effect when compared to early infection and vehicle control ($p<0.05$).

Three groups of mice were treated with varying intravenous doses of R327 (100, 500, 1,000 mg/kg) which showed significant dose-dependent antibacterial effect when compared to early infection control and vehicle control ($p<0.05$). Furthermore, three groups from the 12 were treated with varying intravenous doses of R111 (50, 100, 250 mg/kg) which showed a significant dose-dependent antibacterial effect when compared to early infection control and vehicle control ($p<0.05$).

Azithromycin was the positive control in the study given twice daily at 200 mg/kg and showed bactericidal effect when compared to vehicle control at five-days post infection ($p<0.05$).

[2] https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf

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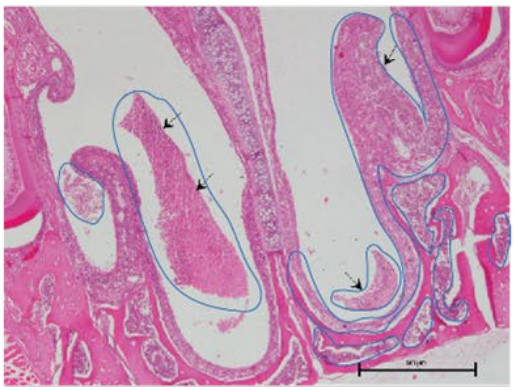
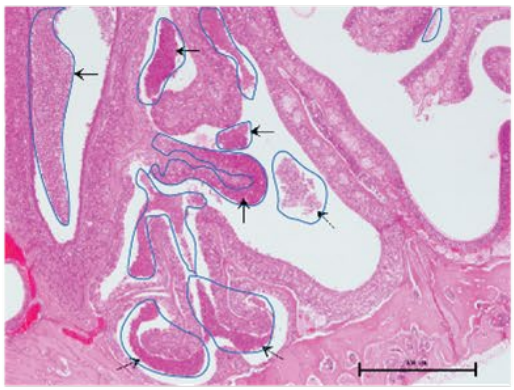
Early Infection Control

Multiple Neutrophils

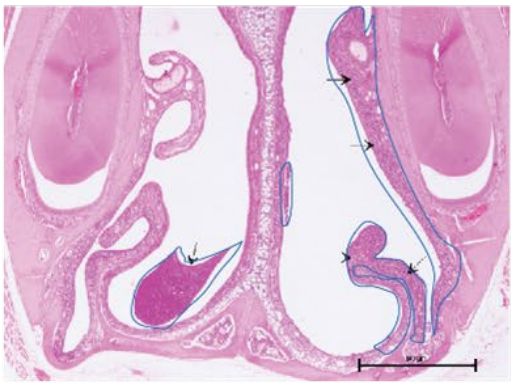


Multiple Neutrophils

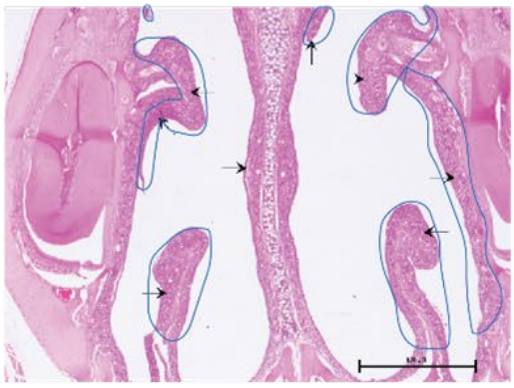


Positive Control IN* - Azithromycin

Multiple Neutrophils

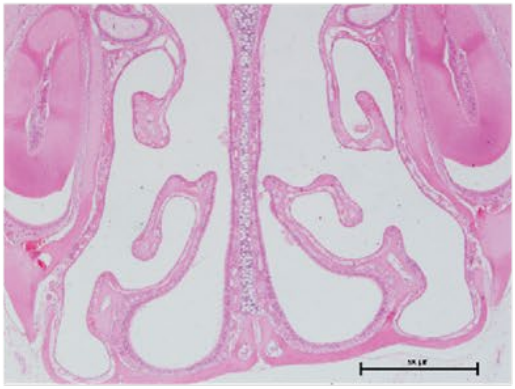


Multiple Neutrophils



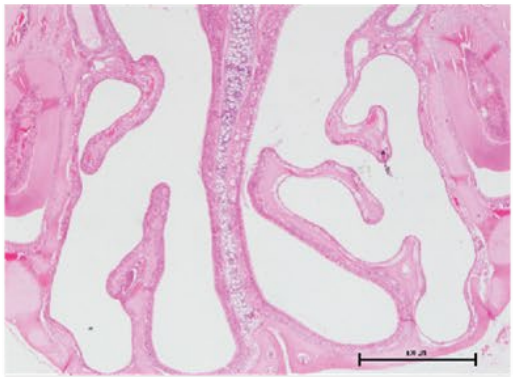
R327 IN* Low dose

Healthy Sinus Cavities - No Abnormality Detected



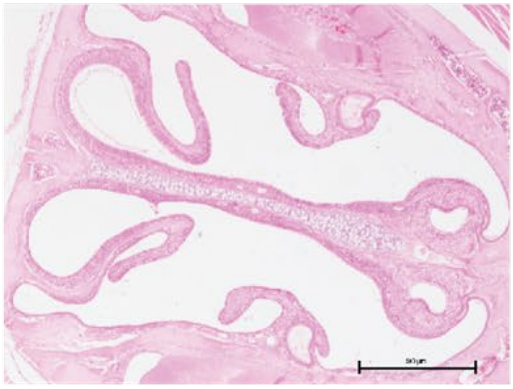
R327 IN* Low dose

Minimal Neutrophils



R111 IV** Low dose

Healthy Sinus Cavities - No Abnormality Detected



R111 IV** Mid dose

Healthy Sinus Cavities - No Abnormality Detected

* Intranasal ** Intravenous

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The Company's R327 and R111 compounds showed significant antibacterial capability with no abnormalities detected and are expected to be subject to further expanded sinusitis studies in due course. In addition to these studies, the Company's clinical activities with R327 continues to progress in the background and looks forward to updating shareholders in due course.

James Graham, Chief Executive Officer of Recce Pharmaceuticals said, "We're continually excited by the potential of Recce's anti-infective compounds and are encouraged by these positive indications. Moreover, this further enhances the breadth of Recce's synthetic polymer platform."

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

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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX:RCE, FSE:R9Q) is pioneering the development and commercialisation of New Classes of Synthetic Anti-Infectives designed to address the urgent global health problems of antibiotic resistant superbugs and emerging viral pathogens.

Recce's anti-infective pipeline is unique and comprised of broad-spectrum synthetic polymer antibiotics RECCE® 327, RECCE® 435 and RECCE® 529 for viral infections with unique mechanisms of action against hyper-mutation on bacteria and viruses, respectively.

Patented lead candidate RECCE® 327 has been developed for the treatment of blood infections and sepsis derived from *E. coli* and *S. aureus* bacteria – including their superbug forms. Recce's new antibiotic compound, RECCE® 435, has been formulated for oral use.

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. Further to this designation, RECCE® 327 has been included on The Pew Charitable Trusts *Global New Antibiotics in Development Pipeline* as the only synthetic polymer drug candidate for treating sepsis currently in development.

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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