ASX Announcement

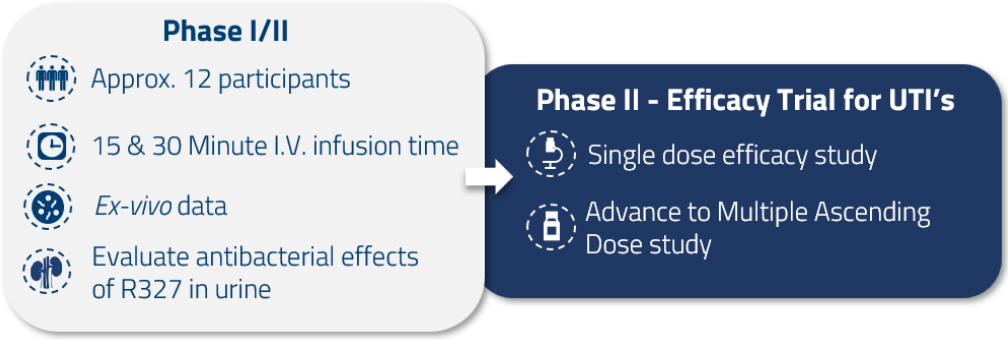
Recce Pharmaceuticals Selects CMAX Research Facility for Phase I/II Urinary Tract Infection Clinical Trial

Highlights:

- **Phase I/II UTI clinical trial of RECCE® 327 (R327) as a fast (15 and 30 mins), 'first-line' treatment**
- ***In-vitro* efficacy of R327 in human urine reduced *E. coli* effectively to irreversibly low levels**
- **If successful, this trial would be indicative of strong therapeutic potential against UTI infections (simple, complicated & recurring) across all medical treatment settings - initial stage (medical practice) and advanced stage (hospital)**
- **Adelaide's CMAX clinical trial facility selected – building upon the success of recent Phase I (I.V.) Safety/Tolerability studies**
- **First subjects expected to be dosed at Q1 2023**

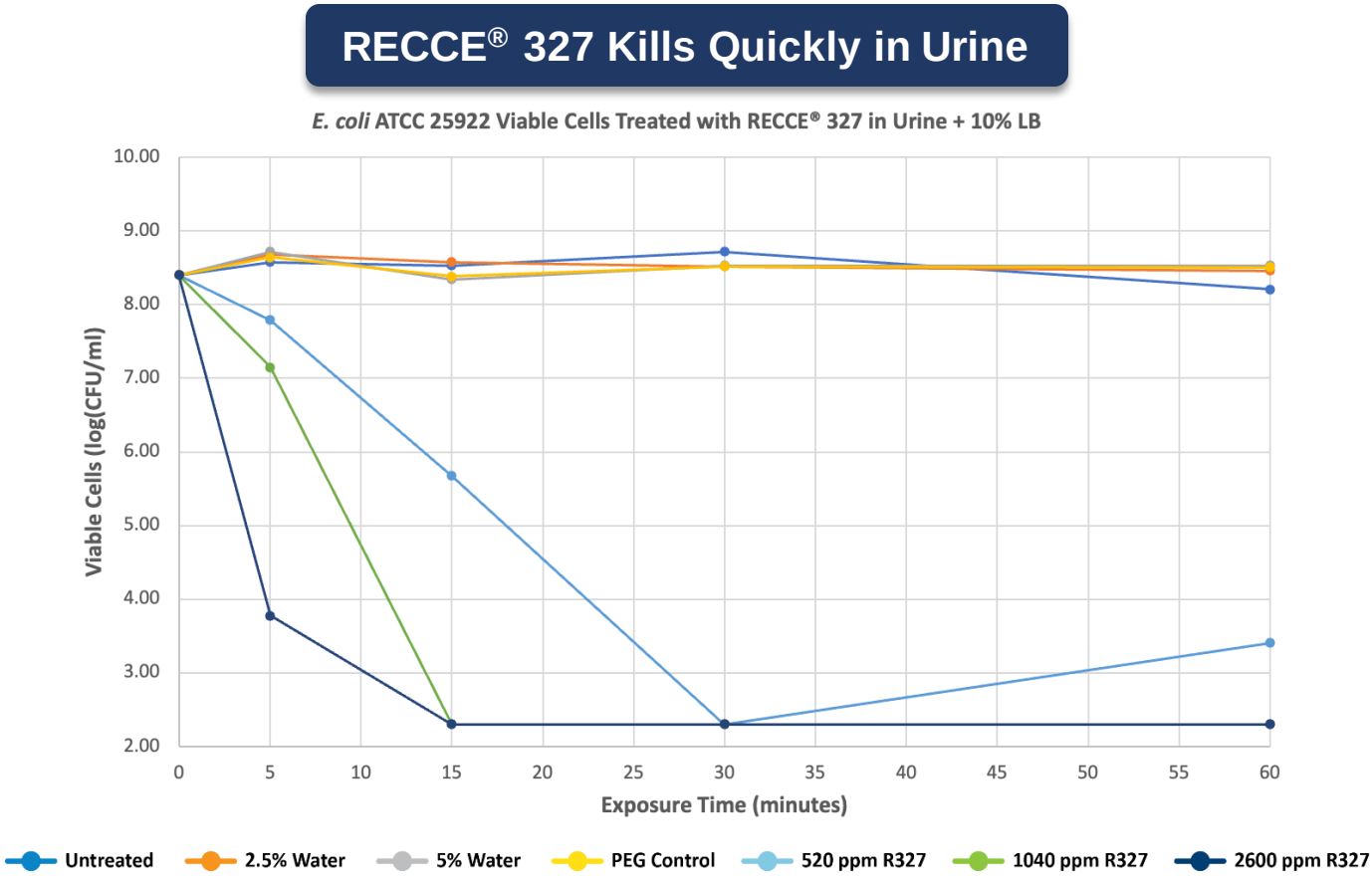
SYDNEY Australia, 20 February 2023: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing a New Class of Synthetic Anti-infectives, today announced it has selected South Australia's CMAX Clinical Research as the independent trial facility to conduct a Phase I/II intravenous (IV) clinical trial of its lead pipeline candidate RECCE® 327 (R327) in healthy male and female subjects.

The trial will look to evaluate and assess R327 as an intravenous dose at faster infusion rates (**15 minutes and 30 minutes**) across three cohorts (**approximately 12 participants**). Plasma and urine will be collected at various time points during and following dosing to evaluate R327's concentrations and antibacterial effect in the urine on various bacterial strains.



The results of this Phase I/II trial will support the advancement of R327 as a broad-spectrum anti-infective across the full spectrum of UTIs (simple, complicated & recurring) as a fast (15 or 30 mins) UTI treatment, with a Phase II in UTI patients expected to be initiated H2 CY23.

An independent *in-vitro* study demonstrated R327 in the presence of human urine was able to have a fast (near minutes) effect against *E. coli* bacteria (responsible for approximately 90% of UTI's[1]) and irreversible (bacteria could not be 'washed out' and regrown) capability starting from comparatively low concentrations of R327.



Understanding logs *(example of a small colony of 1 million MRSA bacteria[2])**
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

[1] https://www.ucsfhealth.org/conditions/urinary-tract-infections
[2] https://halosil.com/what-are-logs-and-why-do-they-matter-in-preventing-infections/

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Further, a recent Phase I study demonstrated R327 could be administered safely – and achieve concentrations in the urine which were 20-fold those achieved in plasma. A healthy bladder is one free from bacteria and the opportunity for R327, clearly identified at the typical site of infection in such high concentrations, strongly supports a potential therapeutic application.

There are no drug therapies currently approved for the treatment of sepsis[3]. UTI's are responsible for about 30% of all sepsis infections, defined as 'Urosepsis'[4]. R327's potential as a treatment option across the patient infectious disease journey (underlying infection>septic state) therefore positions it for therapy in this area of unmet medical need.

Recce Pharmaceuticals Chief Executive Officer James Graham said, "We are thrilled to be building upon the successes of a recent Phase I study with the team at CMAX. The opportunity of showcasing R327's potential to change the treatment paradigm for patients suffering from serious infections, strengthens its position as a fast-acting, broad-spectrum anti-infective."

Dr Nicholas Farinola, Principal Investigator said, "We are highly encouraged by the safety and tolerability of R327 throughout the Phase I trial and are committed to supporting ground-breaking medical research. A high concentration of R327 in the human bladder (some 20-fold) suggests R327 may be used as a broader anti-infective treatment in urosepsis."

CMAX conducts successful world-leading research for local and international clients, specialising in a range of early-phase trials and first-in-human studies.

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

[3] https://www.sciencedirect.com/science/article/pii/S0163725820300048
[4] https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-022-07538-5

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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: **RCE**, FSE: **R9Q**) is developing 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 includes three patented, broad-spectrum, synthetic polymer anti-infectives: RECCE® 327 as an intravenous and topical therapy that is being developed for the treatment of serious and potentially life-threatening infections due to Gram-positive and Gram-negative bacteria including their superbug forms; RECCE® 435 as an orally administered therapy for bacterial infections; and RECCE® 529 for viral infections. Through their multi-layered mechanisms of action, Recce's anti-infectives have the potential to overcome the hypercellular mutation of bacteria and viruses – the challenge of all existing antibiotics to date.

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 world's only synthetic polymer and sepsis drug candidate in development. RECCE® 327 is not yet market approved for use in humans with further clinical testing required to fully evaluate safety and efficacy.

Recce wholly owns its automated manufacturing, which is supporting present clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of its technologies targeting synergistic, unmet medical needs.

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