Safety Committee Approves Faster Infusion Rate of 15 Minutes in Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial

Highlights:

- **Independent Safety Committee approves next Cohort dosing of RECCE® 327 (R327) at a faster infusion rate of 15 minutes of 3,000mg via intravenous administration (I.V)**
- **Independent Safety Committee unanimously agreed R327 is safe and well tolerated in male and female subjects at previous infusion rate of 30 minutes of 3,000mg via I.V administration**
- **R327 has been administered over 1-hour infusion rate and a 30-minute infusion rate of 3,000mg in males and females in previous cohorts – considered to be safe and well tolerated**
- **Next Cohort of Subject Recruitment well underway - subject dosing to begin imminently**

SYDNEY Australia, 24 October 2023: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing a new class of Synthetic Anti-infectives, is pleased to report an Independent Safety Committee has approved next cohort dosing at a **faster infusion rate of 15 minutes of 3,000mg**. Furthermore, the committee unanimously agreed R327 at an infusion rate of 30 minutes of 3,000mg is safe and well tolerated in male and female subjects. The next cohort of subjects have been recruited with dosing to begin imminently.

The Company has previously administered R327 over a 1-hour infusion rate and a 30-minute infusion rate of 3,000mg and was considered by the Independent Safety Committee to be safe and well tolerated. Receiving the committee's go-ahead to proceed with dosing R327 at a **15-minute infusion rate of 3,000mg** is a positive indication of R327s advancement as a broad-spectrum anti-infective across the full spectrum of UTIs (simple, complicated and recurring) through to their all-out septic state 'Urosepsis'. UTI's are responsible for about 30% of all sepsis infections, defined as 'Urosepsis'[1] hence these

[1] https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-022-07538-5

clinical studies are aimed at positioning R327 potential as first patient presentation 'fast-in-fusion' theory designed to stop any bacterial infection in its tracks.

Antibiotics administered as an intravenous infusion (usually over 30 minutes) have benefits such as savings in nursing time, reduced costs and improved safety. In an outpatient setting, I.V rapid infusion of antibiotics is further useful, as the speed of medication infusion can impact the number of patients treated, patient wait times, and duration that patients are connected to infusers[2]. The 2021 Surviving Sepsis Campaign (SCC) guidelines strongly recommend that the administration of intravenous broad-spectrum antibiotics should be initiated as soon as possible, preferably within an hour of sepsis recognition.[3]

Chief Executive Officer of Recce Pharmaceuticals James Graham said "We are pleased to receive the Independent Safety Committee's approval to commence dosing of R327 at an even faster infusion rate (15 minutes) than what has been already administered in previous doses (1-hour infusion rate and a 30-minute infusion rate). This data reaffirms R327's potential first-line treatment for patients suffering from life-threatening infections such as urosepsis or sepsis - as the mortality of sepsis increases by 6-8% for every hour that treatment is delayed."

More information on this trial can be found at the Australia New Zealand Clinical Trial Registry under the trial ID ACTRN12623000448640.

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

[2] https://www.ijidonline.com/article/S1201-9712(21)00574-9/fulltext
[3] https://pubmed.ncbi.nlm.nih.gov/34605781/

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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: **RCE**, FSE: **R9Q**) is developing a New Class 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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