

ASX Announcement

Recce Pharmaceuticals Receives Ethics Approval for RECCE® 327 Faster Infusion, Phase I/II Clinical Trial Expansion

Highlights:

- **The Faster Infusion, Phase I/II UTI Intravenous (IV) study dosing at CMAX Clinical Research expands to Scientia Clinical Research**
- **Human Research Ethics Committee approval allows for further dosing at Scientia Clinical Research, broadening patient population across multiple world class facilities**

Sydney Australia, 29 June 2023: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**), the Company developing a New Class of Synthetic Anti-Infectives, is pleased to announce it has received approval from the Human Research Ethics Committee (HREC) to expand its Faster Infusion, Phase I/II Urinary Tract Infections (UTI) intravenous clinical trial of its lead product, RECCE® 327 (R327), to Scientia Clinical Research.

The clinical trial is assessing R327 at faster administration rates, potentially applicable for use at first patient presentation within a GP or Acute patient setting. R327 will be administered in approximately 16 participants as a broad spectrum anti-infective across the full spectrum of UTIs (simple, complicated & recurring), with a Phase II in UTI patients expected to be initiated H2 CY23.

Scientia Clinical Research is an FDA audited world-class clinical trials facility in Sydney, New South Wales, Australia, specialising in first-in-human and first-in-patient studies, as well as single and multiple dose studies, food effect studies, drug interaction studies, ethnopharmacology, formulation studies. It is co-located in a major research precinct with Prince of Wales Hospital, Royal Hospital for Women, UNSW and the Lowy Cancer Research Centre.

Chief Executive Officer James Graham said: “We are pleased to expand our Phase I/II UTI studies with Scientia Clinical Research (NSW) joining present dosing at CMAX (SA). This now multistate study expects to expedite our clinical trial progress and address the global health threats posed by UTIs and Urosepsis.”

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 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.