ASX Announcement

Recce Completes 5,000 RECCE® 327 Doses a Week under Good Manufacturing Practice (GMP)

Highlights:

- **Successful production of 5,000 x RECCE® 327 (R327) doses per week under Good Manufacturing Practises (GMP) campaign.**
- **R327 manufactured under GMP standards in support of present Phase I, Phase II and anticipated Registrational Phase III clinical trials, demonstrating compliance with guidelines set by regulatory authorities, such as the U.S. Food and Drug Administration.**

Sydney Australia, 16 April 2024: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**), (the **Company**) developing a New Class of Synthetic Anti-Infectives, is pleased to announce the successful batch completion under Good Manufacturing Practices (GMP) for RECCE® 327 (R327) with the patented manufacturing process now producing 5,000 GMP doses of R327 per week.

This week, the Company temporarily transported its manufacturing equipment from its Macquarie Park Facility to a third-party cleanroom-GMP facility, where it produced an increased quantity of 5,000 R327 doses (under GMP) including the final step of the manufacturing cycle – fill and finish.

The manufacturing process is normally completed in-house, where the product is then transferred to a specialist clean room facility for GMP fill and finish. Due to the increased demand of R327 required for clinical studies, producing 5,000 doses of R327 per week is a significant achievement that provides surplus sample material for multiple present Phase I, Phase II and an anticipated Registrational Phase III Diabetic Foot Ulcer Infection study ahead.

This marks a first for Recce's full-spectrum manufacturing capability including demonstrating the versatile, reproducible nature of its patented manufacturing process.

GMP certification signifies compliance with rigorous guidelines set by regulatory authorities, including the U.S. Food and Drug Administration (FDA), ensuring that these doses can be used in Recce's human clinical trials. This progress not only emphasises the commitment to advancing this innovative antibiotic for patients in need but also represents a significant step

towards the Company's Investigational New Drug (IND) submission.

GMP covers all aspects of production, from the starting materials, premises and equipment to the training and personal hygiene of staff. It prevents errors that cannot be eliminated through quality control of the finished product, without GMP it is impossible to be sure that every unit of a medicine is of the same quality as the units of medicine tested in the laboratory.[1]

Recce Pharmaceuticals' Head of Manufacturing Arthur Kollaras said "We are thrilled to announce the successful batch completion of human pharmaceutical grade R327, representing a crucial step forward in our mission to address the global threat of antimicrobial resistance."

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

[1] https://www.who.int/news-room/questions-and-answers/item/medicines-good-manufacturing-processes#:~:text=GMP%20prevents%20errors%20that%20cannot,medicine%20tested%20in%20the%20laboratory.

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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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