ASX Announcement

Independent Safety Committee Approves Expansion of Phase I/II Clinical Trial for Diabetic Foot Infection Treatment

Highlights:

- **Independent Safety Committee unanimously agrees Phase I/II clinical trial is safe, well tolerated and fit for expanded access**
- **Study achieving primary endpoints of safety, tolerability, and efficacy by resolving/curing bacterial infections in diabetic foot ulcers**
- **Patients treated with RECCE® 327 either daily or every second day for 14 days – considered to be safe and well tolerated**
- **Additional clinical sites to be launched in Australia and additional clinical trials will be launched internationally, in diabetic foot infections**

Sydney Australia, 26 February 2024: Recce Pharmaceuticals Limited (**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 unanimously agreed that the ongoing Phase I/II Diabetic Foot Infection (DFI) clinical trial is achieving its primary endpoints and recommended to expand based on the interim data analysis of the patients that were successfully treated with RECCE® 327 (R327).

R327 potential as a topical broad-spectrum anti-infective treatment is the objective of this clinical trial. An Independent Safety Committee of Liverpool Hospital NSW has completed review of all clinical data confirming the study is achieving its primary endpoints of safety and efficacy through either daily or second daily application of R327 resolving/curing bacterial infections in diabetic foot ulcers.

All parties involved have agreed to a broadening of patient description and stage of diabetic foot ulcer infection to award greater patient access to the potential benefits of joining the Liverpool Hospital NSW Clinical trial, managed out of the Ingham Institute for Applied Medical Research. Recce has undertaken to further build-out upon the successes taking place within this clinical study to include additional study sites both locally and overseas which are expected to come online in near months.

Of the estimated 537 million people worldwide who have diabetes, 19% to 34% will develop a Diabetic foot ulcer (DFU) in their lifetime. Approximately 20% of people who develop a DFU will require lower-extremity amputation, either minor (below the ankle), major (above the ankle), or both.[1]

Professor Hugh Dickson, Director of Ambulatory Care at Liverpool Hospital and Principal Investigator of the trial and said, “I am greatly encouraged by the speed at which my patients Diabetic Foot Ulcer infections have responded to R327 when applied topically. A non-invasive method to treat the burdensome challenges of diabetic foot ulcer infections gives hope to better patient outcomes and avoid limb amputation as is so commonly the case with these complicated patients. We thank the independent committee's recognition of the many world-firsts taking place in this DFI clinical trial and welcome expanded access to patients both here at Liverpool Hospital and medical settings beyond.”

Chief Executive Officer of Recce Pharmaceuticals James Graham said, “We are pleased with the decision of the independent committee. We look forward to seeing the potential of R327 utilised as a treatment option in patients suffering from DFIs, offering a chance at a better quality of life without the devastating consequences of amputation.”

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

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9797649/

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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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