ASX Announcement

Phase II Clinical Trial for Acute Bacterial Skin and Skin Structure Infections Recruitment Passes Halfway

Highlights:

- **Topical Phase II clinical trial assessing efficacy of RECCE® 327 topical gel (R327G) against Acute Bacterial Skin and Skin Structure Infections recruitment passes halfway – patients successfully dosed**
- **R327G indicating promising antibacterial effect across a broad range of human infections**
- **Clinical study review board on track for mid-October with interim results to follow**
- **Clinical trial study locations expand across NSW and Victoria, broadening access to this novel treatment**

Sydney Australia, 9 October 2024: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**), (the **Company**), the Company developing a New Class of Synthetic Anti-Infectives, is pleased to announce the successful dosing of 15 patients in its Phase II Acute Bacterial Skin and Skin Structure Infections (ABSSSI) clinical trial. ABSSSI includes diabetic foot infections (DFI) and other wound infections – areas of significant unmet medical need.

RECCE® 327 topical gel (R327G) showing to be safe and well tolerated across human subjects, with indications of promising antibacterial responses observed in patients. These initial data represent a significant opportunity to expand the application of R327G formulation.

ABSSSIs are a significant healthcare concern, with clinical trials addressing indications such as DFIs, necrotizing fasciitis, and post-operative wound infections. The global ABSSSI market size was estimated to be USD $1.34 billion in 2023 and is expected to reach USD $2.31 billion in the next 10 years.

The Phase II clinical trial is an Open-label, Pilot Efficacy Study and Exploratory Evaluation of the Systemic Bioavailability of Single and/or Multiple Doses of R327 as a Topical Gel Applied to Acute Bacterial Skin and Skin Structure Infections, designed to evaluate the efficacy and systemic absorption of R327G when applied directly to the infected area. The study is on track to enrol 30 participants within this calendar year.

In addition to the lead site Barwon Health, the Company has now added two new sites with the Australian Clinical Research Network NSW and ACRN Melbourne.

Chief Executive Officer James Graham said: “We are thrilled to pass the halfway point of this pivotal Phase II clinical study for the unmet clinical need of topical skin infections. Indications of promising antibacterial effect is a significant achievement, with patient recruitment to be completed within the year.”

Mr. Graham further commented, “The market for ABSSSI is expanding as a result of an increase in the frequency of bacterial skin infections, particularly those brought on by drug-resistant strains. The acute lack of effective broad-spectrum antimicrobials contributes significantly to this challenge. Together with our initial data from the Therapeutic Goods Administrations (TGA) Special Access Scheme, which saw dramatic results in a number of DFI patients, we are excited to complete this trial and moreover, the potential of R327G to impact this growing global healthcare need.”

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 (R327) 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 (R435) as an orally administered therapy for bacterial infections; and RECCE® 529 (R529) for viral infections. Through their multi-layered mechanisms of action, Recce's anti-infectives have the potential to overcome the processes utilised by bacteria and viruses to overcome resistance – a current challenge facing existing antibiotics.

The World Health Organization (WHO) added R327, R435, and R529 to its list of antibacterial products in clinical development for priority pathogens, recognising Recce's efforts to combat antimicrobial resistance. The FDA granted R327 Qualified Infectious Disease Product designation under the Generating Antibiotic Initiatives Now (GAIN) Act, providing Fast Track Designation and 10 years of market exclusivity post approval. R327 is also included on The Pew Charitable Trusts' Global New Antibiotics in Development Pipeline as the sole synthetic polymer and sepsis drug candidate in development.

Recce wholly owns its automated manufacturing, supporting current clinical trials. Recce's anti-infective pipeline aims to address synergistic, unmet medical needs by leveraging its unique technologies.

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