ASX Announcement

Recce Pharmaceuticals
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ACN 124 849 065

Recce Pharmaceuticals Receives Ethics Approval to Centralise and Broaden RECCE® 327 Gel Clinical Trials across all Topical Bacterial Skin Infections

Highlights:

- **Positions RECCE® 327 (R327) Gel as potential broad application topical therapeutic for all bacterial skin infections, formally referred to as complicated skin and soft tissue infections with Phase II Diabetic Foot Infection and Wound Infection clinical studies centralised**
- **Human Research Ethics Committee approval received for Phase II clinical trial of R327 topical gel for testing against Acute Bacterial Skin and Skin Structure Infections (ABSSSI), including Diabetic Foot and Wound infections across large unmet medical needs**
- **Study to be conducted by Barwon Health - one of the largest and most comprehensive regional health services in Australia, alongside other existing leading healthcare providers**
- **New site initiation commenced with first patients to be dosed Q3 2024**
- **This trial builds upon clinical results received in testing R327 against Infected Burn Wounds and Diabetic Foot Infections – including patients treated under the TGA Special Access Scheme Category A initiative**

SYDNEY Australia, 24 June 2024: Recce Pharmaceuticals Ltd (**ASX: RCE**, **FSE: R9Q**) (the **Company**), the Company developing a new class of Synthetic Anti-infectives, is pleased to announce it has received Human Research Ethics Committee (HREC) approval to commence a Phase II clinical trial assessing RECCE® 327 (R327) as a topical, broad-spectrum gel applied to Acute Bacterial Skin and Skin Structure Infections (**ABSSSI**).

The Phase II clinical trial is an Open-label, Efficacy Study and Exploratory Evaluation of the Systemic Bioavailability of Single and/or Multiple Doses of R327 Topical Gel Applied to ABSSSI. The study aims to provide critical data on the gel's effectiveness in treating a broad range of ABSSSI indications. ABSSSI refers to a bacterial infection of the skin and its related tissues. Examples of skin conditions commonly included in that category are Diabetic Foot Infections (DFI), necrotizing fasciitis, post operative wound infections and more.

This study approval allows the Company to bring together the clinical studies of DFI, wound infections and more, under one key centralised regulatory category of ABSSSI for a broad range of unmet medical needs in the topical bacterial infection landscape. This centralised study approach to the broad category of ABSSSI has been made possible by building upon and validation of our study data to date, including compelling patient outcomes under the TGA Special Access Scheme Category A initiatives. The purpose of this study is to evaluate R327 gel clinical efficacy and toxicity.

The Company is working with Barwon Health, one of the largest and most comprehensive regional health services in Australia, working alongside existing leading healthcare providers to broaden the scope of its topical administration. This will enable the trial to access a diverse patient population and provide valuable insights on the gel's performance across various ABSSSI conditions.

Recce Pharmaceuticals CEO, James Graham, stated, "Obtaining HREC approval marks another significant milestone for Recce and the clinicians striving to discover an effective treatment for ABSSSIs. This accomplishment highlights Recce's history of successful HREC approvals and underscores the dedication of our clinical and research team as we advance our topical treatment programs."

Significant ABSSSI Opportunity

The global ABSSSI treatment market size was valued at $7.3B USD in 2018 and is projected to reach $26B USD by 2032, representing a CAGR of 9.5% between 2019 and 2032.[1]

ABSSSIs present a considerable challenge to the healthcare system. While new antibiotic treatments have recently been developed to combat Gram-positive organisms, there remains a crucial need for antibiotics that can address both Gram-positive and Gram-negative pathogens. Furthermore, the rise of antimicrobial resistance in both Gram-positive and Gram-negative bacteria, particularly methicillin-resistant *Staphylococcus aureus* (MRSA), presents a growing challenge in treating these infections[2]; with a particular focus on the increase of prevalence of MRSA being detected among hospitalised patients. Those particularly at high risk of skin infections and poor outcomes from ABSSSI are diabetic patients.[3]

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

[1] https://www.fortunebusinessinsights.com/industry-reports/acute-bacterial-skin-and-skin-structure-infections-absssi-treatment-market-100971
[2] https://www.altmeyers.org/en/dermatology/absssi-132569
[3] https://www.sciencedirect.com/science/article/pii/S0168822721000851

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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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