

Acute Bacterial Skin and Skin Structure Infections Phase II Clinical Trial Patient Dosing Advances to Final Stages

Highlights:

- Phase II clinical trial for Acute Bacterial Skin and Skin Structure Infections (ABSSSI) reaches dosing milestone, with 20 of the 30 total patients dosed
- All patients dosed met the primary endpoints of the study either a cure or notable improvement following treatment with RECCE® 327 Topical Gel (R327G)
- Patient dosing on track to be completed within CY24

Sydney Australia, 5 November 2024: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**), (**Recce** or the **Company**), the Company developing a New Class of Synthetic Anti-Infectives, is pleased to announce it is nearing completion of its Phase II clinical trial of RECCE® 327 Topical Gel (R327G) targeting Acute Bacterial Skin and Skin Structure Infections (ABSSSI). With 20 patients now dosed (of 30 total patients), interim data underscores R327G promising efficacy and safety profile.

Data demonstrates a strong therapeutic response, with all patients completing treatment with R327G achieving positive outcomes, showing either complete cure or notable improvement. No Serious Adverse Events (SAEs) have been reported for R327G.

Dr Alan W Dunton, Chief Medical Advisor of Recce Pharmaceuticals said "These interim results reflect a remarkable advancement in our journey to address critical unmet medical needs in anti-infective therapies. The robust response we are seeing with R327G is encouraging, especially as we near completion of the Phase II trial. Achieving a response of complete cure or notable improvement in all patients treated so far highlights the potential impact of R327G in treating complex bacterial infections, including diabetic foot infections."



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As the trial progresses towards completion within CY2024, the Company remains focused on delivering a pioneering, synthetic anti-infective topical therapy to address ABSSSI, a market estimated to reach USD26 billion by 2032¹. This continuation, following the non-DSMB's unanimous endorsement, reflects the positive trajectory of R327G's development and supports its continued progress toward regulatory evaluation.

For further information on this trial, please refer to the Australia New Zealand Clinical Trial Registry, trial ID ACTRN12624000973516.

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

¹ <https://www.grandviewresearch.com/industry-analysis/acute-bacterial-skin-and-skin-structure-infections-absssi-market-report>



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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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