ASX Announcement

Recce Pharmaceuticals
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ACN 124 849 065

All Patients Dosed in Phase II Clinical Trial of RECCE® 327 Topical Gel in Acute Bacterial Skin and Skin Structure Infections

Highlights:

- **All patients (30) dosed in Phase II clinical trial assessing efficacy of RECCE® 327 topical gel (R327G) in Acute Bacterial Skin and Skin Structure Infections**
- **Preliminary data indicates patients experienced either a complete cure or significant improvement in infection symptoms following treatment with R327G**
- **Full analysis of Phase II results due in Q1 2025**
- **Advancement of additional Australian regulatory trials to be initiated in H1 2025**

Sydney Australia, 21 January 2025: 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 the successful dosing of all 30 patients in its Phase II clinical trial of RECCE® 327 Topical Gel (R327G) for the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI).

The Phase II clinical trial is an open-label study to evaluate the safety and tolerability, plasma pharmacokinetics, and efficacy of R327G; applied once daily for 7 or 14 days to areas infected by ABSSSI.

Phase II interim data has demonstrated there were no Serious Adverse Events (SAEs) with R327G's efficacy and safety profile, and patients dosed achieving positive outcomes. The full set of clinical data will be reviewed by the Data Safety Monitoring Board with full Phase II results expected to be announced in Q1 2025. Recce is expected to initiate a Phase III study of R327G in Australia in H1 2025 that will serve as a registrational trial for the US Food and Drug Administration (FDA) and Australian Therapeutic Goods Administration (TGA).

Separately, the Company has received approval to initiate a Registrational Phase III clinical trial assessing R327G for the treatment of diabetic foot infections (DFIs) in Indonesia. The trial will be one of the largest DFIs studies in the world[1] and the first of its kind across Indonesia, bringing

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8351150/

forward commercial opportunities for the Company in the ASEAN region.

James Graham, CEO of Recce Pharmaceuticals said: "R327G has made significant progress over the last year, confirming its safety profile and demonstrating impressive efficacy as a topical gel formulation, especially considering the high degree of bacterial resistance present in many of the patients being treated in this Phase II trial. We look forward to the full dataset, which we expect will further support R327G's progress toward regulatory evaluation."

Dr Alan W Dunton, Chief Medical Advisor of Recce Pharmaceuticals said "We are thrilled to see such robust clinical results from our Phase II trial. These results demonstrate the potential of R327G to address the ABSSSI market. This milestone marks significant progress in our clinical development journey."

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.[2] ABSSSI refers to a bacterial infection of the skin and its related tissues. Examples of skin conditions commonly included in that category are DFIs, necrotizing fasciitis, postoperative wound infections and more.

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. The FDA has increased its focus on the critical role of new antibiotics, specifically broad-spectrum antibiotics (such as R327G) in addressing antimicrobial resistance (AMR), particularly when immediate treatment is required, or the pathogen is unknown.[3] Treatments effective against both Gram-positive and Gram-negative bacteria, enable a rapid response to resistant and mixed bacterial infections. Those particularly at high risk of skin infections and poor outcomes from ABSSSI are diabetic patients.[4]

Further information on this trial can be found at the Australia New Zealand Clinical Trial Registry under the trial ID ACTRN12624000973516.

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

[2] https://www.fortunebusinessinsights.com/industry-reports/acute-bacterial-skin-and-skin-structure-infections-absssi-treatment-market-100971
[3] https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/antimicrobial-resistance
[4] 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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