ASX Announcement

Recce Pharmaceuticals Receives Interim Efficacy Data and Safety Approval to Continue Phase II ABSSSI Clinical Trial

Highlights:

- **Non-Data Safety Monitoring Board unanimously agree RECCE® 327 Topical Gel (R327G) is safe and well-tolerated in patients – R327G demonstrating highly encouraging efficacy results**
- **All patients completing treatment with R327G had a positive primary endpoint - achieving either complete cure or improvement, seen as early as 7 days**
- **No Serious Adverse Events noted in patients - recommendation for clinical trial to continue, reflecting promising potential of R327G as a safe and effective treatment for Acute Bacterial Skin and Skin Structure Infections including Diabetic Foot Infections**

Sydney Australia, 28 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 that an independent non-Data Safety Monitoring Board (non-DSMB) has completed its review of safety and efficacy data from the Company's ongoing Phase II clinical trial of its lead compound, RECCE® 327 Gel (R327G), in patients with Acute Bacterial Skin and Skin Structure Infections (ABSSSI) including diabetic foot infections (DFI).

In their review, the non-DSMB found no safety concerns and unanimously recommended continuing the clinical trial which is on-track to be completed within the calendar year. This decision was based on R327G's excellent safety profile, with no serious adverse events (SAE) observed in patients and highly encouraging efficacy results.

Most patients treated with R327G demonstrated highly encouraging efficacy results, with all patients completing treatment being positive on the primary endpoint and achieving either complete cure or improvement, with many showing complete cure results as early as 7 days. These outcomes were measured using the Lipsky Clinical Resolution of Infection Scale (Lipsky Scale), a widely recognised tool for assessing the resolution of infections, particularly in diabetic

foot infections. Recognised by the FDA, the Lipsky Scale is an approved and reliable method for evaluating the treatment of wound infections. The non-DSMB's positive findings further underscore the strong safety profile of Recce's innovative anti-infective therapy.

Patient ID	Age/Gender	Infection	Clinical Response
Patient 1	88/Male	ABSSSI	Cure (Day 7)
Patient 2	53/Male	ABSSSI	Cure (Day 7)
Patient 3	49/Male	ABSSSI	Cure (Day 7)
Patient 4	63/Female	ABSSSI	Cure (Day 7)
Patient 5	46/Male	ABSSSI	Cure (Day 14)
Patient 6	63/Female	ABSSSI	Cure (Day 14)
Patient 7	67/Male	ABSSSI	Improvement (Day 7)
Patient 8	72/Male	ABSSSI	Improvement (Day 7)
Patient 9	70/Male	ABSSSI	Improvement (Day 7)
Patient 10	59/Male	ABSSSI	Improvement (Day 7)
Patient 11	63/Male	ABSSSI	Improvement (Day 7)
Patient 12	68/Male	ABSSSI	Improvement (Day 14)
Patient 13	81/Female	ABSSSI	Withdrawn*
Patient 14	84/Female	ABSSSI	Improvement (Day 14)

*While no serious adverse events were noted, one patient was discontinued due to pain at the wound site which was judged to be unlikely related to R327G.

The conditions treated included diabetic foot ulcer, eczema, scratch and puncture wound infections. A wide variety of infecting bacteria (Gram positive and Gram negative) were isolated and successfully treated with Improvement/Cure of infection in all patients that continued with their treatment.

Professor Eugene Athan, Coordinating Principal Investigator of the study, said: "We're seeing some very promising results from the interim data in the Phase II trial, which confirm the safety and potential efficacy of R327G in treating Acute Bacterial Skin and Skin Structure Infections, including diabetic foot infections."

CEO, James Graham, commented: "We are extremely encouraged by the feedback from the non-Data Safety Monitoring Board and the ongoing safety and efficacious profile of R327G. The absence of serious adverse events, coupled with the wide range of broad-spectrum efficacy across challenging wound infections, reinforces the potential of R327G to address unmet medical needs in the treatment of serious bacterial infections."

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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].

The title of 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 and is designed to evaluate the efficacy and systemic absorption of R327G when applied directly to the infected area.

More 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.

[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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