ASX Announcement

Recce Pharmaceuticals
recce.com.au
ACN 124 849 065

RECCE® 327 added to The World Health Organization's List of Antibacterial Products in Clinical Development

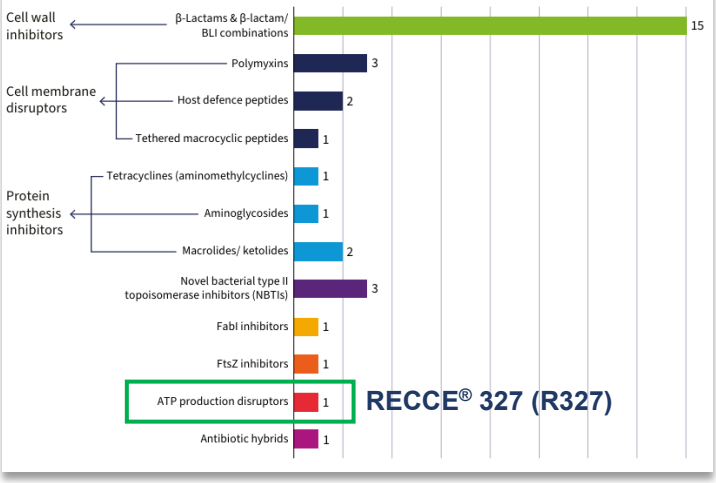
Highlights:

- **Global recognition by the World Health Organization (WHO) – inclusion underscores significance of RECCE® 327 (R327) in combating antimicrobial resistance**
- **Unique Mechanism of Action – R327 uniquely classified as an adenosine triphosphate (ATP) production disruptor, the only compound under this category**
- **R327 recognised as a novel treatment for a broad range of life-threatening and resistant bacteria**

SYDNEY Australia, 18 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 its primary anti-infective candidate, RECCE® 327 (R327), has been added to the World Health Organization's (WHO) report of Antibacterial Agents in Clinical Development and Preclinical Development.

The report covers traditional and non-traditional antibacterial agents in development worldwide and evaluates to what extent the present pipeline addresses infections caused by priority pathogens, according to the updated 2024 WHO bacterial priority pathogens list.

Fig. 10. Distribution of traditional agents according to their antibiotic class



R327 has been defined by the WHO as an ATP production disruptor **and is the only compound under this category**. ATP is the source of energy for use and storage at the cellular level. Disruption of ATP production in bacterial cells when targeted as the main mechanism of action, not secondary to other cell perturbation mechanisms, carries the potential to confer activity against both Gram-positive and Gram-negative pathogens.

Annex 13. ATP production disruptors

Product name (INN or company code):
RECCE 327 (R327)

Pharmacology: chemical class and MoA: RECCE 327 (R327) is a fully synthetic (acrolein) polymer designed to disrupt bacterial energy (ATP) production, cell growth and division.

Spectrum of activity and potential resistance: In vitro (poster) data suggest broad-spectrum antibacterial activity against MDR strains of Gram-positive and Gram-negative bacteria, including *Enterococcus faecium*, *S. aureus*, *K. pneumoniae*, *A. baumannii*, *P. aeruginosa* and *Enterobacter* spp. (Recce Pharmaceuticals, unpublished data, 2021) (1). In vivo (poster) activity in these "ESKAPE" pathogens has also been described in mouse model studies for kidney and UTI bacterial infection (Recce Pharmaceuticals, unpublished data, 2021) (1).

Sought therapeutic indication: RECCE 327 is being studied as a broad-spectrum intervention in infected burn wound care and diabetic foot infection, and in cUTI/urosepsis caused by ESBL-producing Enterobacteriaceae.

Route of administration and proposed posology: Intravenous and topical gel/spray.

Phase of clinical development: Recent completion of a Phase 1 single iv ascending dose safety and PK study with no publications as yet. Commencement of a Phase 1b/2a proof-of-concept trial for topical application of RECCE 327 for mild diabetic foot infections is planned (2).

Clinical trial(s): Four trials are listed in the Australian New Zealand Clinical Trials Registry:

- ACTRN12621001313820: a Phase 1 ascending-dose, randomized, placebo-controlled, parallel, double-blind, single-dose, first-in-human study to evaluate the safety and PK of RECCE 327 in 80 healthy male subjects 18–55 years of age (June 2021 to December 2022, completed);
- ACTRN12623000448640: a Phase 1 open-label, adaptive design evaluation, crossover study of the safety and PK/PD of various RECCE 327 intravenous dose and infusion rates;
- ACTRN12623000056695: a Phase 1/2 proof-of-concept study of RECCE 327 topical anti-infective therapy for mild skin and soft tissue diabetes foot infections; and
- ACTRN12621000412831: a Phase 1 proof-of-concept study of RECCE 327 topical antibiotic therapy for infected burn wounds in adults.

Preclinical PK and safety: In vivo poster data describe no adverse clinical signs in rats treated with RECCE 327, and it achieved broad distribution with particular concentration in urine (Recce Pharmaceuticals, unpublished data, 2021). In tests comparing 50 mg/kg and 500 mg/kg of R327 to vehicle control, the antibacterial effect was dose-dependent ($P < 0.050$) (Recce Pharmaceuticals, unpublished data, 2021) (1).

Chief Executive Officer of Recce Pharmaceuticals, James Graham, said, "We are pleased that R327 has been included in the list of antibacterial products aimed at tackling the urgent global health threat posed by antibiotic resistance. There is a demand for new antibiotic therapies, and this report further showcases R327's potential as a novel treatment for a broad range of life-threatening and resistant bacteria."

View the full WHO Antibiotic pipeline here: https://www.recce.com.au/WHO-report.pdf

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

recce.com.au
ACN 124 849 065

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

Media and Investor Relations

Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Jordyn Temperato
LifeSci Communications
jtemperato@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com

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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Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

Media and Investor Relations

Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Jordyn Temperato
LifeSci Communications
jtemperato@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com