

Recce Pharmaceuticals Ltd

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New class of synthetic antibiotics set to tackle superbugs

Recce Pharmaceuticals is commercializing a novel synthetic broad-spectrum antibiotic designed to overcome antimicrobial resistance. Its lead compound, RECCE 327, is one of the first entirely new classes of antibiotics to be developed in more than 30 years.

RECCE 327 developed by Recce Pharmaceuticals Ltd (ASX:RCE) has destroyed every bacterium it has been tested against, including superbugs, and has proved invulnerable to any attempt by bacteria to mutate and overcome its mechanism of action.

The promising new drug is currently in the final preclinical stages with preparations underway for first-in-human clinical trials. Recce's new compound is a broad-spectrum antibiotic initially to be used intravenously against *Escherichia coli* and *Staphylococcus aureus* bacteria in the blood, including superbug forms.

In a sign of growing global interest, Australian-based Recce has been awarded qualified infectious disease product (QIDP) designation by the US Food & Drug Administration (FDA).

The QIDP designation, awarded under the Generating Antibiotic Initiatives Now (GAIN) Act, means the antibiotic has fast track designation along with 10 years of market exclusivity post-approval.

"It is a completely new class of broad-spectrum antibiotic that will kill all bacteria, including superbugs. Even when bacteria attempt to mutate, the antibiotic continues to work," said VP James Graham.

Traditionally, antibiotics have come from natural sources, for instance penicillin, or are modified to achieve broad-spectrum activity. Using a so-called 'lock and key' mechanism at the cellular level, these drugs lock into a specific part of the bacterial membrane and attack it. Once the bacteria mutate, the antibiotic is rendered useless.

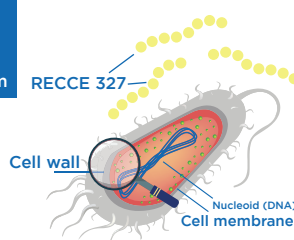
A universal mechanism

"The antibiotic mechanism is novel, universal and can be considered as the master key," Graham said. "It locks on to the bacterial membrane, reacts with the protein and kills the bacteria. Its unique action and composition means it can overcome any attempt by bacteria to mutate. There are no signs that its potency lessens, even with repeated use" (Fig. 1).

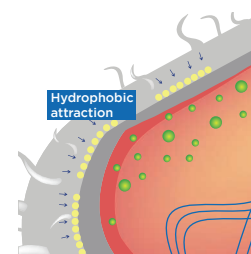
Based on a patented polymeric structure, Recce's antibiotic has millions of active sites, compared with only one, two or three active sites of traditional antibiotics.

Recce VP and co-inventor of the technology, Michele Dilizia, said it was widely acknowledged that antimicrobial resistance (AMR) was one of the world's most urgent unmet medical issues. "Multidrug-resistant bacteria cause the deaths of more than 700,000 people annually, and millions more have serious complications from infections. AMR is forecast to kill up to 10 million people annually by 2050 unless solutions are found," she said.

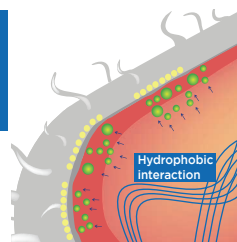
Step 1
RECCE 327
Enters the
blood stream



Step 2
RECCE 327
Binds to outer
membrane of
bacteria



Step 3
RECCE 327
Interacts with
bacterial plasma
membrane proteins



Step 4
Bacteria bursts,
redundant bacteria
absorbed

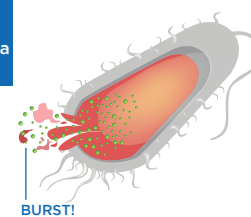


Fig. 1 | The universal mechanism of RECCE 327. The compound binds to the outer membrane of bacteria, interacts with bacterial plasma membrane proteins causing the bacteria to burst.

As well as their ability to mutate, bacteria can also acquire resistance from other bacteria through gene transfer. Global over-use of antibiotics in agriculture and animal husbandry, as well as over-prescribing, has compounded the problem.

Antibiotic development has stalled

Almost every antibiotic on the market today is based on scientific discoveries made more than 30 years ago. Development of new antibiotics has faltered, owing to a lower return on investment compared with drugs used for long-term chronic conditions. Doctors avoid prescribing new antibiotics for fear they will dilute their potency.

Underscoring the urgent need for new antibiotic solutions, Recce is permitted to supply RECCE 327 to Australian medical practitioners in defined circumstances under the Australian Therapeutic Goods Administration (TGA) Special Access Scheme Category A.

"In the absence of an industry response, a number of forward-looking institutions including governments, medical groups, private enterprise and the World Health Organization are now urgently working to address the growing threat of AMR," Dilizia said.

"New initiatives include additional support for R&D costs, acceleration of regulatory pathways, extended market exclusivity and the removal of market barriers."

"RECCE 327's approval for QIDP designation

underscored the potential of synthetic polymers as a new class of antibiotics," said co-inventor, VP and chief research officer, Graham Melrose. "RECCE 327 was developed primarily to address the unmet need globally to treat blood infections and sepsis resulting from *E. coli* and *S. aureus* bacteria," continued Melrose. "Currently there are no antibiotics specifically for treating sepsis, so there is a huge and urgent need for effective, safe treatments."

The technology can be delivered in various formulations and treat a range of infections; e.g. an oral formulation is planned for *Helicobacter pylori* bacteria.

Melrose said the technology would revolutionize the antibiotic business model. "RECCE 327 will keep on working, despite any bacterial mutations. It will never lose its effectiveness and physicians will have great confidence in prescribing it."

The American market is strongly in Recce's sights, as it comprises about 47% of the antibiotic market.

Recce will maintain manufacturing operations in Australia.

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