

Japanese pharma firm Shionogi receives marketing approval in Australia for antibiotic Cefiderocol

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Agreement with Link Medical Products for the development and commercialisation of cefiderocol in Australia and New Zealand



Japan-based Shionogi has received marketing authorisation from the Therapeutic Goods Administration (TGA) in Australia for cefiderocol, a siderophore cephalosporin developed by Shionogi for the treatment of carbapenem-resistant Gram-negative bacterial infections.

This marketing authorisation is based on the results of three global clinical trials of cefiderocol conducted to date: the Phase 2 APEKS-cUTI study in patients with complicated urinary tract infections (cUTI), the Phase 3 CREDIBLE-CR study in patients with carbapenem-resistant Gram-negative bacterial infections, and the Phase 3 APEKS-NP study in patients with hospital-acquired pneumonia.

The TGA has approved cefiderocol for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis, and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia due to proven or strongly suspected carbapenem-resistant aerobic Gram-negative organisms in adults with limited treatment options.

Shionogi has entered into a license agreement with Link Medical Products for the development and commercialisation of cefiderocol in Australia and New Zealand. Following the marketing authorisation in Australia, Shionogi will work with Link to improve access to this novel antibacterial agent for patients who need it.

Treatment options remain limited, making antimicrobial resistance (AMR) one of the areas with a significant unmet medical need. Cefiderocol is active against Gram-negative bacteria, including a range of multidrug-resistant bacteria that have become difficult to treat due to the acquisition of antimicrobial resistance, and the marketing authorisation is expected to provide a new treatment option for patients with these infections.