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News

Cumberland's Vibativ injection gains China's NMPA approval

The launch of the injection in the country is anticipated during 2025.

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Vibativ is tailored to combat ventilator-associated and hospital-acquired pneumonia caused by Gram-positive bacteria. Credit: mi_viri/Shutterstock.

Cumberland Pharmaceuticals' antibiotic Vibativ (telavancin) injection has gained approval from China's National Medical Products Administration (NMPA), offering a new treatment option for patients with severe bacterial infections.

The approval comes after the company's agreement with SciClone Pharmaceuticals granted it exclusive rights to register, promote and distribute this US Food and Drug Administration (FDA)-approved injection in China.

The antibiotic, which can be administered once a day without the need for therapeutic drug monitoring, aims to reduce healthcare professionals' exposure to patients.

The companies plan the injection's launch in the country in 2025.

SciClone Pharmaceuticals CEO, president and executive director Zhao Hong stated: "Vibativ's life-saving potential for patients with certain difficult-to-treat infections makes it an important addition to our portfolio and supports our mission to provide quality medical products that improve patient care.

"We strongly believe in this product and look forward to providing it to patients in China."

As an injectable anti-infective, Vibativ is tailored to combat ventilator-associated and hospital-acquired pneumonia caused by various Gram-positive bacteria.

It is also aimed against complicated skin and skin structure infections (cSSSIs), such as those caused by methicillin-resistant staphylococcus aureus (MRSA).

Discovered through a dedicated research programme, Vibativ targets serious infections caused by Staphylococcus aureus (S aureus) and other Gram-positive bacteria, encompassing both MRSA and methicillin-susceptible strains.

The injection has in vitro potency and bactericidal activity within six hours.

Vibativ is also approved in the Middle East and the US for treating adults with hospital-acquired and ventilator-associated bacterial pneumonia when alternative treatments are unsuitable.

It also gained approval for cSSSIs caused by susceptible Gram-positive bacteria.

In May 2023, the US FDA expanded the labelling for Cumberland Pharmaceuticals' Caldolor therapy to include use in infants.