BioSpectrum the business of Bio & Health Sciences

Merck's new drug fast-tracked by FDA

09 September 2014 | News | By BioSpectrum Bureau

Merck's new drug fast-tracked by FDA

Merck's, relebactam an investigational beta-lactamase inhibitor, has been granted a Qualified Infectious Disease Product (QIDP) with fast-track status by the US regulator. The speedy assessment applies to intravenous use of relebactam for complicated urinary tract and intra-abdominal infections and hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia.

In pre-clinical studies, it has demonstrated antibacterial activity against a broad range of gram-negative and beta-lactam resistant pathogens.

QIDP designation offers certain incentives for the development of new antibiotics, including a five-year extension of data exclusivity and priority review of the New Drug Application (NDA) when filed.

Mr Nicholas Kartsonis, head of infectious disease, Merck research laboratories, said, "The lack of new medicines to fight drug-resistant infections is a growing public health concern. We look forward to working with the FDA and other experts in infectious disease to study this medicine with the goal of bringing it to people suffering from potentially life-threatening resistant bacterial infections as quickly as possible."

Relebactam is being evaluated in combination with imipenem/cilastatin in Phase II trials. Merck plans to initiate Phase III studies for the combination next year.