BioSpectrum the business of Bio & Health Sciences

US FDA fast tracks MedImmune's Pneumonia drug

26 September 2014 | News | By BioSpectrum Bureau

US FDA fast tracks MedImmune's Pneumonia drug

MedImmune, AstraZeneca's global biologics research and development arm, has received a fast track designation from the US Food and Drug Administration (US FDA) for its investigational monoclonal antibody (mAb) MEDI3902 for the prevention of nosocomial pneumonia. The disease is caused by Pseudomonas aeruginosa (P. aeruginosa), a highly drug-resistant bacterial pathogen that causes serious illness in hospitalised patients.

MEDI3902, currently entering Phase I clinical trials, is a novel mAb engineered to combine three distinct mechanisms of action for disarming and clearing P. aeruginosa. In pre-clinical trials, MEDI3902 was found to produce enhanced effects for both prevention and treatment of the problematic bacterial infection in multiple animal models. Prophylactic use of MEDI3902 will be investigated as a potentially new therapeutic approach for controlling pneumonia in hospitalized patients.

"We are pleased that the FDA has granted Fast Track designation for MEDI3902, recognising the unique science behind this investigational monoclonal antibody and the importance of accelerating development of new medicines that may help prevent serious bacterial infections, such as nosocomial pneumonia, rather than solely relying on antibiotics to treat them," said Mr Steve Projan, senior vice president, R&D and Infectious Diseases and vaccines iMED head, MedImmune. He added, "At a time when antimicrobial resistance poses an imminent and urgent global public health threat, it's more important than ever to develop new therapies that both prevent and treat hospital acquired infections. The Fast Track designation will streamline communications with the FDA throughout the development process on what is a very different approach to the bacterial resistance problem. If successful, we hope to bring this important new medicine to patients as quickly as possible."

MedImmune is exploring ways of using biologics to help prevent and treat challenging infectious diseases, including P. aeruginosa.