BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Tetraphase antibiotic gets FDA QIDP designation

July 22, 2013 | Regulatory | By BioSpectrum Bureau



Singapore: US-based Tetraphase Pharmaceuticals has received approval from US FDA for its lead antibiotic product candidate, eravacycline, as a Qualified Infectious Disease Product (QIDP).

QIDP designation, granted for complicated intra-abdominal infection (cIAI) and complicated urinary tract infection (cUTI) indications, will make eravacycline eligible to benefit from certain incentives for the development of new antibiotics provided under the Generating Antibiotic Incentives Now Act (GAIN Act).

Eravacycline is being developed as a broad-spectrum IV and oral antibiotic for use as a first-line empiric monotherapy for the treatment of multi-drug resistant infections, including multi-drug resistant Gram-negative infections. Tetraphase is planning to advance eravacycline into Phase 3 clinical studies in cIAI and cUTI in the second half of this year.

"We are delighted that our lead antibiotic product candidate, eravacycline, has received QIDP designation under the GAIN Act for both cIAI and cUTI indications. We believe it is the first product candidate to receive this designation in cIAI," said Mr Guy Macdonald, Tetraphase president and CEO. "Antibiotic resistance, particularly among the difficult-to-treat populations with Gram-negative infections, represents a potential global health crisis."

The GAIN Act, Title VIII (Sections 801 through 806) of the FDA Safety and Innovation Act, seeks to provide pharmaceutical and biotechnology companies with incentives to encourage the development of new drugs to treat, prevent, detect and diagnose antibiotic-resistant infections. Qualifying pathogens are defined by the GAIN Act to include multi-drug resistant Gram-negative bacteria, including *Pseudomonas, Acinetobacter, Klebsiella, and Escherichia coli* species; resistant Gram-

positive pathogens, including *methicillin-resistant Staphylococcus aureus (MRSA)*, vancomycin-resistant *Staphylococcus aureus* and vancomycin-resistant *Enterococcus*; multi-drug resistant tuberculosis; and *Clostridium difficile*.