

Thermo Fisher Scientific Launches Complementary Diagnostic Immunoassay Measuring Plazomicin Concentrations

FREMONT, Calif., Dec. 10, 2018 /PRNewswire/ -- Thermo Fisher Scientific has received FDA clearance for its de novo submission of the [Thermo Scientific QMS Plazomicin Immunoassay](#), the first of its kind for complementary diagnostic immunoassays. This quantitative immunoassay measures the concentration of a novel therapeutic antibiotic, plazomicin, using the automated clinical chemistry analyzer, Beckman Coulter AU 680. Plazomicin (trade name ZEMDRI¹) is a next-generation aminoglycoside being used to treat patients with complicated urinary tract infections (cUTI).

The new QMS Plazomicin Immunoassay is the latest addition to the Thermo Fisher line of therapeutic drug monitoring (TDM) immunoassays, which employ proprietary technology across a range of drug classes including those for antibiotics, antiepileptics, antiarrhythmics, immunosuppressants, and others. Thermo Scientific TDM immunoassays enable physicians to monitor and administer therapeutics on an individual patient basis. By maintaining optimized drug levels, the effects of under or over dosage may be minimized and patient outcome improved.

This immunoassay was developed in collaboration with Achaogen, Inc., a biopharmaceutical company with expertise in innovative antibacterial drug development to address multi-drug resistant (MDR) gram-negative infection. "The commercialization of our FDA cleared QMS Plazomicin immunoassay is representative of our continued commitment to meet the needs of our biopharmaceutical development partners and the patients whom they serve. QMS TDM immunoassays are liquid, ready-to-use and designed to provide precise and accurate measurement of drug levels in patients," said Lonnie Shoff, president clinical diagnostics at Thermo Fisher.

"Therapeutic drug monitoring aims to improve patient outcomes and reduce costs. The measurement of levels of plazomicin in blood will enable TDM-adjusted plazomicin dosing in recommended patient populations," said Janet Dorling, chief commercial officer at Achaogen. "Monitoring plazomicin drug levels with accuracy and precision has been an important goal and, with the achievement of this regulatory milestone, we are excited about the commercialization of the QMS Plazomicin Immunoassay from Thermo Fisher."

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