GenMark Diagnostics Announces FDA Submission of its ePlex Blood Culture Identification Gram-Negative and ePlex Blood Culture Identification Fungal Pathogen Panels

October 2, 2018

Submissions Now Complete for All Three ePlex Molecular Multiplex Panels Designed for the Diagnosis and Management of Bloodstream Infections That Can Lead to Sepsis

CARLSBAD, Calif., Oct. 02, 2018 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (NASDAQ:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced the submission of two additional ePlex Blood Culture Identification Panels – the Gram-Negative (BCID-GN) Panel and Fungal Pathogen (BCID-FP) Panel - to the U.S. Food and Drug Administration (FDA). These panels, together with the ePlex BCID Gram-Positive (BCID-GP) Panel previously submitted to the FDA in June 2018, are being developed on the Company's ePlex sample-to-answer system, for the diagnosis and disease management of bloodstream infections that can lead to sepsis.

"The submissions of our BCID-GN and BCID-FP panels to the FDA signify our continued commitment to ePlex menu expansion, which is one of GenMark's top priorities. Sepsis is a global healthcare priority and we are confident that our ePlex BCID solution will improve the management of patients with blood stream infections and help combat antibiotic resistance," said Hany Massarany, President and Chief Executive Officer.

About GenMark Diagnostics

GenMark Diagnostics (NASDAQ: GNMK) is a leading provider of multiplex molecular diagnostic solutions designed to enhance patient care, improve key quality metrics, and reduce the total cost-of-care. Utilizing GenMark's proprietary eSensor® detection technology, GenMark's eSensor XT-8® and ePlex® systems are designed to support a broad range of molecular diagnostic tests with compact, easy-to-use workstations and self-contained, disposable test cartridges. GenMark's ePlex: The True Sample-to-Answer Solution™ is designed to optimize laboratory efficiency and address a broad range of infectious disease testing needs, including respiratory, bloodstream, and gastrointestinal infections. For more information, visit www.genmarkdx.com.

Forward Looking Statements

This press release includes forward-looking statements regarding events, trends and business prospects, which may affect our future operating results and financial position. Such statements, including, but not limited to, those regarding the timely FDA clearance and commercialization of additional ePlex panel menu, are all subject to risks and uncertainties that could cause our actual results and financial position to differ materially. Some of these risks and uncertainties include, but are not limited to, our ability to successfully obtain regulatory clearance in the United States for our ePlex BCID panels, the commercialization our ePlex system and its related test menu in a timely manner, constraints or inefficiencies caused by unanticipated acceleration and deceleration of customer demand, our ability to successfully expand sales of our product offerings outside the United States, and third-party payor reimbursement to our customers, as well as other risks and uncertainties described under the "Risk Factors" in our public filings with the Securities and Exchange Commission. We assume no responsibility to update or revise any forward-looking statements to reflect events, trends or circumstances after the date they are made.

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