GenMark Diagnostics Announces FDA Submission of its ePlex Blood Culture Identification Gram Positive Panel

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First of Three ePlex Molecular Multiplex Panels for the Diagnosis and Management of Bloodstream Infections That Can Lead to Sepsis

CARLSBAD, Calif., June 28, 2018 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (NASDAQ:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced submission of its ePlex Blood Culture ID – Gram Positive (BCID-GP) panel to the U.S. Food and Drug Administration (FDA). The BCID-GP panel is the first of three blood culture panels being developed on the ePlex sample-to-answer system, for the diagnosis and disease management of bloodstream infections that can lead to sepsis. The Company anticipates FDA submission of the Gram Negative panel (BCID-GN) and the Fungal Pathogen panel (BCID-FP) in the third and fourth quarters of this year, consistent with prior communication.

“The FDA submission of our ePlex BCID-GP panel marks an important milestone for GenMark, as we continue to expand our menu of multiplex molecular panels across multiple infectious diseases. We designed the ePlex BCID-GP panel to offer the broadest pathogen inclusivity and drug resistance markers of any multiplex molecular solution on the market today and believe it will meaningfully improve the management of patients with blood stream infections and provide a new tool to help address the growing public health crisis of antibiotic resistance,” said Hany Massarany, President and Chief Executive Officer. “We’ve also recently initiated the clinical study for our BCID-GN panel and we’re in the final stages of preparation for the BCID-FP clinical study. Based on this, we continue to expect to submit these panels to FDA later this year,” noted Massarany.

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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