GenMark Diagnostics Receives FDA 510(k) Market Clearance for its ePlex Blood Culture Identification Gram-Positive Panel

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CARLSBAD, Calif., Dec. 20, 2018 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (NASDAQ:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced that it has received FDA 510(k) market clearance from the U.S. Food and Drug Administration (FDA) for its ePlex Blood Culture Identification Gram-Positive (BCID-GP) Panel. This panel, together with the ePlex Blood Culture Identification Gram-Negative (BCID-GN) and Fungal Pathogen (BCID-FP) Panels, were developed for the diagnosis and disease management of bloodstream infections (BSI) that can lead to sepsis.

Developed on the ePlex sample-to-answer system, the BCID Panels deliver novel benefits designed to improve patient care and antimicrobial stewardship (AMS) with the broadest organism inclusivity and resistance gene coverage. By coupling GenMark's BCID Panels with the ePlex "Templated Comments" software module, hospitals can enable immediate intervention linked to a diagnostic result and improve effectiveness of AMS initiatives. The ePlex BCID-GP Panel includes important BSI causing pathogens and unique targets to aid in rapidly ruling out blood culture contamination.

"We are excited to offer customers additional tools to improve the identification and management of bloodstream infection. Additionally, our ePlex software platform links results from these tests to localized antimicrobial stewardship guidelines to help guide treatment decisions, which will save critical time for patients and healthcare providers alike," said Hany Massarany, President and Chief Executive Officer. "Test menu expansion will remain a priority for us as we continue our diligent development and clinical efforts to unlock the full potential of the ePlex system. We are pleased to exit the year with two FDA cleared panels, and with the BCID-GN and BCID-FP Panels in the later stages of the regulatory process."

GenMark's BCID-GN and BCID-FP Panels were submitted to the FDA in September 2018 and are still currently under review.

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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Source: GenMark Diagnostics, Inc.