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

April 15, 2019

Complete Suite of ePlex Blood Culture Identification Panels Now Available in the U.S.

CARLSBAD, Calif., April 15, 2019 (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-Negative (BCID-GN) Panel. This is the third ePlex BCID Panel to receive FDA clearance during the past four months. GenMark's complete family of ePlex BCID Panels, including the Gram-Negative (BCID-GN), Gram-Positive (BCID-GP) and Fungal Pathogen (BCID-FP) Panels, were developed on the Company's ePlex sample-to-answer system for the diagnosis and disease management of bloodstream infections (BSI) that can lead to sepsis.

"The ePlex BCID Panels provide broad coverage of organisms and resistance markers that can lead to sepsis, including anaerobes and multidrug resistant organisms (MDRO), as well as common and emerging fungal pathogens. We are excited to bring to market the most comprehensive molecular test solution designed to improve the diagnosis and management of bloodstream infections, while delivering economic and quality benefits to our customers," said Hany Massarany, President and Chief Executive Officer. "We believe that the potential market opportunity for our BCID Panels could be as large as the available market for our Respiratory Pathogen (RP) Panel, which we estimate to be around $500 million globally. We expect BCID to be a key contributor to our 2019 performance, driving both ePlex placements and assay sales," added 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 financial and operational impacts of our BCID Panels, 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 commercialize our ePlex system and its related test menu in a timely manner, including our BCID Panels, 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.