GenMark Diagnostics Receives FDA 510(k) Market Clearance for its ePlex Blood Culture Identification Fungal Pathogen Panel

December 26, 2018

Two of Three ePlex Blood Culture Identification Panels Now Cleared for Marketing in the U.S.

CARLSBAD, Calif., Dec. 26, 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 Fungal Pathogen (BCID-FP) Panel. This panel, together with the ePlex Blood Culture Identification Gram-Positive (BCID-GP) and Gram-Negative (BCID-GN) Panels, were developed for the diagnosis and disease management of bloodstream infections (BSI) that can lead to sepsis.

The BCID-FP Panel has the broadest coverage of fungal pathogens compared to other commercially available molecular panels and includes many resistant and emerging strains, including *Candida auris*. Fungal pathogens are a growing cause of BSI and are associated with some of the highest mortality rates.

“Receiving FDA clearance for two of our three ePlex BCID panels is an exciting way to end the year,” said Hany Massarany, President and Chief Executive Officer. “Our third panel is currently under review by FDA and we continue to expect its clearance in the early part of next year. We expect BCID to be a key contributor to our 2019 performance, driving both ePlex placements and assay sales.”

GenMark’s BCID-GN Panel was submitted to the FDA in September 2018 and is 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.