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GenMark Diagnostics Submits 510(k) Applications to the FDA for ePlex® Sample-to-Answer Instrument and Respiratory Pathogen Panel

CARLSBAD, Calif.--(BUSINESS WIRE)-- **GenMark Diagnostics, Inc. (Nasdaq:GNMK),** a leading provider of automated, multiplex molecular diagnostic testing systems, today announced that it has submitted 510(k) applications to the FDA for its ePlex sample-to-answer instrument and Respiratory Pathogen Panel.

ePlex will offer comprehensive molecular diagnostic panels on a scalable sample-to-answer system, designed to enable syndromic infectious disease testing in hospital and reference laboratories. The system fully integrates and automates the entire process from nucleic acid extraction and amplification, through detection, interpretation and reporting. Workflow has been optimized requiring approximately two minutes of hands-on time and includes bi-directional integration to Laboratory Information Systems (LIS), a patented technology for positive patient identification, and the ability to provide customer support via remote access. ePlex combines innovative digital microfluidics with GenMark's eSensor® electrochemical detection technology, to enable precise fluid management and accurate results. The ePlex Respiratory Pathogen Panel is designed to detect the most clinically relevant viral and bacterial targets from nasopharyngeal samples. The ePlex instrument and Respiratory Pathogen Panel were launched in Europe in June, 2016.

"We designed ePlex to improve patient outcomes while optimizing laboratory workflow and efficiency. Feedback from European customers and U.S. clinical trial sites reinforces this unique value proposition of ePlex," said Hany Massarany, President and Chief Executive Officer of GenMark. "Our teams continue to focus on the global commercialization of ePlex and the expansion of its menu. We expect our Blood Culture ID family of panels, including the Gram Positive, Gram Negative, and Fungal panels, to be available in Europe during the first quarter of 2017," added Massarany.

ABOUT GENMARK DIAGNOSTICS

GenMark Diagnostics (NASDAQ: GNMK) is a leading provider of automated, multiplex molecular diagnostic testing systems that detect and measure DNA and RNA targets to diagnose disease and optimize patient treatment. Utilizing GenMark's proprietary eSensor® detection technology, GenMark's eSensor XT-8® system is designed to support a broad range of molecular diagnostic tests with a compact, easy-to-use workstation and self-contained, disposable test cartridges. The eSensor detection technology is also incorporated into GenMark's sample-to-answer system, ePlex®. For more information, visit www.genmarkdx.com.

SAFE HARBOR STATEMENT

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 our ePlex instrument and its future test 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 commercialize 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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