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GenMark Receives FDA 510(k) Market Clearance for Its ePlex® Instrument and Respiratory Pathogen Panel

The True Sample-to-Answer Solution™ Brings New Capabilities to Multiplex Molecular Diagnostics

CARLSBAD, Calif.--(BUSINESS WIRE)-- GenMark Diagnostics, Inc. (Nasdaq:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced that it has received 510(k) market clearance from the U.S. Food and Drug Administration for both its ePlex instrument and Respiratory Pathogen (RP) Panel.

ePlex is a transformational new *in vitro* diagnostic platform that integrates nucleic acid extraction, amplification, and detection processes into a fully automated, sample-to-answer system. Rapid and highly specific detection is enabled on ePlex by GenMark's established and proven eSensor® technology, which has been used in more than two million patient tests conducted across multiple FDA-cleared panels on the Company's XT-8 system. The introduction of ePlex to the U.S. market is expected to enhance the benefits of multiplex molecular testing and make them accessible to many more hospitals and patients across the country.

The ePlex RP Panel detects over 20 viral and bacterial pathogens that commonly cause upper respiratory infections. Combining the comprehensive coverage of the ePlex RP Panel with the true sample-to-answer capabilities of ePlex provides physicians access to rapid, accurate, and actionable test results for high risk patients and helps laboratory directors improve productivity through reduced labor costs, advanced data analytics, and best-in-class customer service and support.

"We are very pleased to announce the 510(k) clearance of ePlex and the Respiratory Pathogen Panel. There is a growing body of evidence that rapid, multiplex molecular testing for respiratory pathogens improves patient outcomes, reduces total cost of care, and enhances key quality metrics," said Hany Massarany, President and Chief Executive Officer of GenMark. "We believe that ePlex will help laboratories and hospitals realize these benefits as it is the only sample-to-answer molecular platform that integrates the diagnostic process from test order entry, all the way to reporting actionable results," added Massarany.

"Rapid and accurate diagnosis of respiratory pathogens has been shown to improve outcomes in high risk patients and help hospitals address key priorities such as infection control and antimicrobial stewardship," said Kimberle C. Chapin, M.D., Professor of Pathology and Medicine at Lifespan Academic Medical Centers and Brown Medical School. "We look forward to having GenMark's ePlex technology because it is simple enough to be performed any time of day by multiple personnel and can be easily integrated into a patient care algorithm 24/7. It can provide fast, actionable results that will improve cohorting and patient flow through the ED, reduce unnecessary testing, and support appropriate antimicrobial use, particularly during the peak of respiratory season."

"The Medical Center has relied on GenMark's first-generation eSensor platform for syndromic infectious disease testing to help optimize patient treatment for the past several years," noted Wallace H. Greene, PhD, D(ABMM), Director of Diagnostic Virology Laboratory at Penn State Health Milton S. Hershey Medical Center and one of the investigators in GenMark's RP clinical study. "Our experience has shown that integrating this technology into a sample-to-answer platform like ePlex can further benefit patients with streamlined workflow and a high level of LIS integration to further accelerate the reporting of patient results."

The Company previously announced it had secured over 70 ePlex customer agreements totaling more than 100 analyzers. With FDA clearance achieved, ePlex installations at U.S. customer sites are beginning and revenue from these installations is expected to positively impact the second half of 2017. Accordingly, the Company expects second quarter 2017 revenues in the range of $12 to $13 million. For full year 2017, the Company continues to expect revenue in the range of $65 to $70 million and gross margin in the range of 48-52%.

In connection with achieving FDA clearance for the ePlex instrument and RP Panel, the Company intends to draw down an additional $15 million under the terms of its existing debt facility.

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.

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 our future financial performance, the timely and effective commercialization and clinical impact of our ePlex system, and the availability of future debt financing, 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, third-party payor reimbursement to our customers, our ability to satisfy the conditions to draw down under the terms of our debt facility, 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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