



GenMark Diagnostics Announces Global Shipments of ePlex® RUO Test Kits Designed for SARS-CoV-2 Detection

March 2, 2020

CARLSBAD, Calif., March 02, 2020 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (NASDAQ:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced the initial shipments of ePlex Research Use Only (RUO) test kits designed to detect the SARS-CoV-2 virus. Initial RUO test kits were recently shipped to the company's Hong Kong distributor, as well as several U.S. customers that have access to clinical samples. GenMark plans to use this information to support submission of an Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) for the ePlex SARS-CoV-2 test to address this developing global public health emergency.

"In just one month, our team completed the design, manufacture and shipment of initial tests to customers for validation of our assay design using clinical samples. This is a strong demonstration of the GenMark teams' scientific and operational expertise, the capability of our novel ePlex technology, and our ability to quickly adapt ePlex to meet a specific market need," said Scott Mendel, Interim Chief Executive Officer. "COVID-19 is a global health emergency and we believe it is important to use our technology and resources to contribute in the fight against this disease. We are pursuing FDA's EUA regulatory pathway for this test with the goal to provide broad access to an easy to use, sample-to-answer solution for detection of this emerging virus," concluded Mr. Mendel.

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 our ability to secure an EUA from the FDA for our ePlex RUO SARS-CoV-2 test, 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 demonstrate the clinical performance and utility of our ePlex RUO SARS-CoV-2 test, the continued progression of the associated public health emergency, and 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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