GenMark Diagnostics Announces Submission of Emergency Use Authorization for its ePlex® SARS-CoV-2 Test

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CARLSBAD, Calif., March 11, 2020 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (NASDAQ:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced submission for an Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) for its ePlex SARS-CoV-2 Test. Upon issuance of an EUA, the ePlex test could be utilized by clinical laboratories for detection of SARS-CoV-2. Initial Research Use Only (RUO) tests were shipped last week to several key customers to validate the assay design using clinical samples.

“Our priority was to help our customers address this global health emergency. We leveraged our adaptable and easy-to-use ePlex platform to quickly design and manufacture a test to accurately detect this highly contagious virus in clinical samples,” said Scott Mendel, Interim Chief Executive Officer. “EUA submission in just over a week from the initial RUO shipments of our ePlex test is a critical step to enable our customers to rapidly detect and possibly prevent the spread of the COVID-19 virus.”

“Getting tests to detect COVID-19 in the hands of our physicians and clinicians as soon as possible is one of our highest priorities in combatting this rapidly expanding health emergency,” said Dr. Dwayne Breining, Executive Director of Labs, Northwell Health. “GenMark is an important Northwell partner in molecular diagnostics and we are grateful to their team for continuing to push forward a test that can rapidly identify patients with SARS-CoV-2. We strongly support their efforts to gain an EUA and have provided clinical sample data from our early access to expedite this process.”

GenMark’s request for EUA is currently under review by the FDA. If the FDA concludes that the criteria for issuance of an EUA has been met, the company will begin shipment of test kits to its customers for routine clinical use.

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 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 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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