GenMark Awarded BARDA Grant for the Development of ePlex® RP2 Panel

March 23, 2020

CARLSBAD, Calif., March 23, 2020 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (NASDAQ:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced it has been awarded a grant from the Biomedical Advanced Research and Development Authority (BARDA), part of the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR).

In working with public and private partners to find solutions to mitigate the impact of COVID-19, BARDA will provide GenMark with up to $749,000 in funding to develop and pursue U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) of a diagnostic panel that incorporates the new SARS-CoV-2 viral target into the company's existing ePlex Respiratory Pathogen (RP) panel. With this additional support from BARDA, GenMark expects to be able to complete the development work necessary to request an EUA from the FDA for the ePlex RP2 Panel.

GenMark's ePlex RP2 Panel will leverage the company's ePlex instrument that has been FDA cleared for use with its ePlex Respiratory Pathogen (RP) Panel, Blood Culture Identification (BCID) Panels (Gram-positive, Gram-negative and Fungal pathogens), and most recently the Emergency Use Authorization of a SARS-CoV-2 Test. The FDA has categorized the ePlex system and tests as Clinical Laboratory Improvement Amendments (CLIA) moderately complex, allowing for its use in a broad array of hospital and reference lab settings. The new test will be developed for the qualitative detection of respiratory pathogens in nasopharyngeal swab samples. The addition of the SARS-CoV-2 target to the existing ePlex RP Panel will allow for rapid, streamlined testing for respiratory illnesses, saving time and valuable hospital resources that are critically limited at this time. Recent evidence shows a high percent of COVID-19 patients are also infected with other respiratory viruses, making it even more important to test for a broad panel of respiratory pathogens.

"We are very honored to receive this support from BARDA to continue the development of our ePlex RP2 Panel," said Scott Mendel, Interim Chief Executive Officer. "Providing a single test with comprehensive, rapid and actionable results across a broad range of viral and bacterial pathogens enables improved patient outcomes. Our team fully understands the urgency to develop this expanded RP panel and we will work hard to deliver exactly that."

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 are 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 successfully develop and obtain an EUA from the FDA for our ePlex RP2 Panel, our ability to successfully obtain full IVD clearance of our ePlex SARS-CoV-2 Test from the FDA and demonstrate its clinical performance and utility, the continued progression of the associated public health emergency, our ability to satisfy the supply demands of our customers, 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.

Investor Relations Contact
Leigh Salvo
(415) 937-5404
ir@genmarkdx.com

Source: GenMark Diagnostics, Inc.