Fluidigm Files for FDA Emergency Use Authorization for Saliva-Based Advanta Dx SARS-CoV-2 RT-PCR Test for COVID-19

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Extraction-Free, Real-Time PCR Workflow with Capacity of Up to 6,000 Tests per Day

Easy-to-Administer Saliva Test Would Eliminate Need for Invasive Nasopharyngeal Swab

High-Throughput Assay Developed in Collaboration with Washington University School of Medicine

SOUTH SAN FRANCISCO, Calif., June 12, 2020 (GLOBE NEWSWIRE) -- Fluidigm Corporation (Nasdaq:FLDM), an innovative biotechnology tools provider with a vision to improve life through comprehensive health insight, today announced it has filed for Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for an extraction-free saliva-based test to detect the SARS-CoV-2 virus. The test, developed in collaboration with scientists at the McDonnell Genome Institute and the Department of Genetics at Washington University School of Medicine in St. Louis, provides an easy-to-administer protocol that does not require collection via invasive nasopharyngeal swab and is processed on the Biomark™ HD microfluidics platform.

The Advanta™ Dx SARS-CoV-2 RT-PCR Assay is intended for use by high-complexity labs certified under the Clinical Laboratory Improvement Amendments in the United States. The test would enable health care providers to conduct testing through collection of saliva, which is significantly easier than invasive nasopharyngeal swab collection and could enhance testing coverage in critical populations.

“Rapid, reliable testing that is widely available to the public is essential in combatting the COVID-19 pandemic,” said Jeffrey Milbrandt, MD, PhD, Executive Director of the McDonnell Genome Institute and head of the Department of Genetics at Washington University School of Medicine. “The close collaboration between teams at Washington University and Fluidigm aided our efforts to quickly develop this high-throughput assay for SARS-CoV-2 that relies on a saliva sample. Such a test could help overcome supply chain bottlenecks that have limited testing for COVID-19 and help identify infections.”

The Advanta Dx SARS-CoV-2 RT-PCR test on the Biomark HD platform provides throughput and cost advantages that reduce the impact of capacity-constrained supply chains. The company’s microfluidics technology enables processing of more samples per batch and uses a fraction of expensive testing reagents per sample as compared to more traditional, microwell plate-based PCR technology.

“There’s an urgent need to simplify testing for COVID-19 so that people who are infected can be easily and quickly identified,” said Richard Head, Director of the Genome Technology Access Center at the McDonnell Genome Institute. “The test we developed in collaboration with Fluidigm doesn’t require RNA extraction, a time-consuming and expensive step necessary to other tests for SARS-CoV-2. Our test could be easily scaled up and made widely available.”

Fluidigm will provide updates with regard to timing of broad commercial availability of the Advanta Dx SARS-CoV-2 RT-PCR test.

“Our high-throughput saliva-based test enhances testing capacity and simplifies COVID-19 testing while eliminating the need for hard-to-source components such as extraction kits,” said Chris Linthwaite, President and CEO of Fluidigm. “Speed, scale and early detection have been critically important since the beginning of this health crisis, and the addition of improvements in ease of use — eliminating the invasive nasopharyngeal swab protocol without compromising performance — could make this test a game changer for the next phase of the global pandemic response.

“The Fluidigm approach bends the cost curve, increases ultrahigh-throughput testing capability per system, eliminates the expense and complexity of extraction, and provides a less invasive sample collection process that could open testing access to large numbers of people,” Linthwaite said. “We believe frequent testing of a large percentage of the population is the best path forward, and a critical foundation for getting the global economy back to work.

“We are truly honored for the opportunity to collaborate with Washington University School of Medicine to bring this much-needed innovation in COVID-19 testing.”

The Advanta Dx SARS-CoV-2 RT-PCR Assay is the subject of an EUA filing with the FDA. The FDA may require additional data, validation and/or testing, and may not ultimately provide authorization. An EUA, if granted, does not constitute FDA clearance or approval, but would allow use by authorized laboratories only while the EUA is in effect.

About Fluidigm

Fluidigm (Nasdaq:FLDM) focuses on the most pressing needs in translational and clinical research, including cancer, immunology, and immunotherapy. Using proprietary CyTOF® and microfluidics technologies, we develop, manufacture, and market multi-omic solutions to drive meaningful insights in health and disease, identify biomarkers to inform decisions, and accelerate the development of more effective therapies. Our customers are leading academic, government, pharmaceutical, biotechnology, and plant and animal research laboratories worldwide. Together with them, we strive to increase the quality of life for all. For more information, visit fluidigm.com.

About Washington University School of Medicine
Washington University School of Medicine's 1,500 faculty physicians also are the medical staff of Barnes-Jewish and St. Louis Children's hospitals. The School of Medicine is a leader in medical research, teaching and patient care, as is among the top 10 medical schools in the nation as ranked by U.S. News & World Report. Through its affiliations with Barnes-Jewish and St. Louis Children's hospitals, the School of Medicine is linked to BJC HealthCare.

Forward-Looking Statements for Fluidigm
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, among others, statements regarding the anticipated uses and features of the Advanta™ Dx SARS-CoV-2 RT-PCR Assay if Fluidigm's Emergency Use Authorization is approved by the FDA, its anticipated commercial availability, and its potential impact on COVID-19 testing trends, public health, and the economy. Forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from currently anticipated results, including but not limited to risks relating to the potential adverse effects of the coronavirus pandemic on our business and operating results during 2020; our ability and/or the ability of the research institutions utilizing our products and technology to obtain Emergency Use Authorization from the FDA and any other requisite approvals to use our products and technology for diagnostic testing purposes; potential changes in priorities or requirements for Emergency Use Authorizations; potential limitations of any Emergency Use Authorization; challenges inherent in developing, manufacturing, launching, marketing, and selling new products; risks relating to company research and development and distribution plans and capabilities; interruptions or delays in the supply of components or materials for, or manufacturing of, Fluidigm products; potential product performance and quality issues; intellectual property risks; and competition. Information on these and additional risks and uncertainties and other information affecting Fluidigm business and operating results is contained in Fluidigm's Annual Report on Form 10-K for the year ended December 31, 2019, and in its other filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof. Fluidigm disclaims any obligation to update these forward-looking statements except as may be required by law.

Available Information
We use our website (fluidigm.com), investor site (investors.fluidigm.com), corporate Twitter account (@fluidigm), Facebook page (facebook.com/Fluidigm), and LinkedIn page (linkedin.com/company/fluidigm-corporation) as channels of distribution of information about our products, our planned financial and other announcements, our attendance at upcoming investor and industry conferences, and other matters. Such information may be deemed material information, and we may use these channels to comply with our disclosure obligations under Regulation FD. Therefore, investors should monitor our website and our social media accounts in addition to following our press releases, SEC filings, public conference calls, and webcasts.

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