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

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Easy-to-Administer Saliva Test for COVID-19 Available for Immediate Shipment

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

Demonstrated 100 Percent Agreement with Authorized Nasopharyngeal Assays

SOUTH SAN FRANCISCO, Calif., Aug. 25, 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 received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the Advanta™ Dx SARS-CoV-2 RT-PCR Assay, an extraction-free saliva-based test to detect nucleic acid from the SARS-CoV-2 virus, designed to be run on the Fluidigm® Biomark™ HD microfluidics platform.

Because it is saliva-based, the Advanta Dx SARS-CoV-2 RT-PCR Assay does not require collection via invasive nasopharyngeal swab. The clinical study associated with the EUA submission demonstrated 100 percent agreement between the saliva results from the Advanta Dx SARS-CoV-2 RT-PCR Assay and the results from paired nasopharyngeal samples tested with authorized assays.

“Accessible and accurate testing programs that include a non-invasive, saliva-based collection option will be essential throughout duration of the COVID-19 pandemic”, said Andrew Lukowiak Ph.D, CEO of San Diego-based Millennium Health, one of several high-complexity labs certified under the Clinical Laboratory Improvement Amendments (CLIA) in the United States that has been evaluating the Advanta Dx SARS-CoV-2 RT-PCR Assay in advance of authorization.

“In addition to the attractive sample input we chose the Fluidigm workflow because it combines extraordinary throughput per system with a robust supply chain from a trusted large-scale supplier. We believe this approach will enhance testing coverage in critical populations.”

The Advanta Dx SARS-CoV-2 RT-PCR test on the Biomark HD platform provides throughput advantages that reduce the impact of capacity-constrained supply chains. The company’s microfluidics technology enables processing of more samples per batch than more traditional, microwell plate-based PCR technology. The Biomark HD platform can generate as many as 6,000 test results per day on a single system.

“We have seen extraordinarily strong customer interest in our high-throughput saliva-based test, including many new purchases of Biomark HD systems to enable its adoption,” said Chris Linthwaite, President and CEO of Fluidigm. “We have a high degree of confidence that this new test will not only enhance testing capacity but will also significantly improve speed to results and scale. The ease of use for health care providers and patients alike will enable improved testing access to the global population. Fluidigm is excited to commercialize this easily administered saliva-based COVID-19 test during a critical phase of the pandemic.

“In the United States, Emergency Use Authorization for our test coincides with the total number of COVID-19 cases exceeding 5.7 million, underscoring the need for scalable and easy-to-administer testing.”

Fluidigm was recently selected by the National Institutes of Health, National Institute of Biomedical Imaging and Bioengineering, for a proposed project under the agency’s Rapid Acceleration of Diagnostics (RADx) program. RADx fast-tracks development and commercialization of innovative technologies to significantly increase U.S. testing capacity for SARS-CoV-2.

The project, with a total proposed budget of up to $37 million, contemplates expanding production capacity and throughput capabilities for COVID-19 testing with Fluidigm microfluidics technology. The RADx project envisions both a major expansion of microfluidics manufacturing capacity and commercialization of a novel barcoding chemistry to further increase test throughput per system.

The Advanta Dx SARS-CoV-2 RT-PCR Assay was developed in collaboration with scientists at the McDonnell Genome Institute and the Department of Genetics at the Washington University School of Medicine in St. Louis.

Fluidigm’s ongoing collaboration with the Defense Advanced Research Projects Agency (DARPA) and its Epigenetic CHaracterization and Observation (ECHO) program includes financial support for development of innovative programs based on our microfluidics technology.

The RADx project has been funded in whole or in part with federal funds from the National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Department of Health and Human Services, under contract no. 75N92020C00009.

About Emergency Use Authorization Status

Advanta™ Dx SARS-CoV-2 RT-PCR Assay is a real-time reverse transcription (RT) PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in saliva specimens collected without preservatives in a sterile container from individuals suspected of COVID-19 by their health care provider.

This test has not been FDA cleared or approved. It has been authorized by the FDA under an EUA for use by authorized laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high-complexity tests. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only

authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the authorization is terminated or revoked sooner.

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, plant and animal research and clinical laboratories worldwide. Together with them, we strive to increase the quality of life for all. For more information, visit fluidigm.com.

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 benefits and advantages of the Advanta Dx SARS-CoV-2 RT-PCR Assay, including for expansion of COVID-19 testing, customer demand for and commercialization of the Fluidigm test, total potential funding for Fluidigm under the RADx project, and anticipated completion of a RADx definitive contract and associated benefits to Fluidigm. 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; uncertainties in contractual relationships; our ability and/or the ability of the research institutions utilizing our products and technology to obtain and maintain 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; potential changes in the priorities of government agencies; 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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