Fluidigm Receives CE-IVD Mark for Its Saliva-Based Advanta Dx SARS-CoV-2 RT-PCR Assay for COVID-19

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SOUTH SAN FRANCISCO, Calif., Jan. 21, 2021 (GLOBE NEWSWIRE) -- Fluidigm Corporation (Nasdaq:FLDM), an innovative biotechnology tools provider with a vision to improve life through comprehensive health insight, today announced that the company has received the CE-IVD mark for its Advanta™ Dx SARS-CoV-2 RT-PCR Assay, an extraction-free saliva-based test to detect nucleic acid from the SARS-CoV-2 virus. The CE-IVD mark is in conformance with the European Union *In Vitro* Diagnostic Directive.

The Advanta Dx SARS-CoV-2 RT-PCR Assay does not require collection via invasive nasopharyngeal swab, and the company's clinical studies for submission demonstrated 100 percent agreement between saliva results from the Advanta Dx Assay and results from paired nasopharyngeal samples tested with authorized assays.

A growing body of peer-reviewed research is confirming that the accuracy of saliva-based COVID-19 testing is comparable to that of nasopharyngeal-based collection. A systematic review and meta-analysis published in *JAMA Internal Medicine* in January 2021 stated that saliva-based tests have a similar sensitivity and specificity and present an attractive alternative to invasive nasopharyngeal testing.

"Since introduction of our saliva-based COVID-19 testing solution in the United States, we have seen tremendous interest in our testing technology, and we are gratified by the opportunity to offer one of the first saliva-based COVID-19 tests to be widely available in Europe, where the total addressable market for COVID-19 testing, based on third-party and company estimates, is $5 billion to $7 billion in 2021," said Chris Linthwaite, Fluidigm President and CEO. "The European region is currently reporting a million new infections every four days and has seen more than 27 million cases since the pandemic began.

"In the first phase of the pandemic, we served the European market via home-brew laboratory COVID-19 tests. We are excited for the opportunity to now distribute Fluidigm CE-IVD commercial kits via our direct sales force and distribution partners, including for potential screening applications that may not require an order from a health care provider. We anticipate offering the Advanta Dx SARS-CoV-2 RT-PCR Assay for as little as 5 euros per test, based on volume and other factors.

"This much-needed noninvasive testing solution is being delivered in Europe at a critical time in the global health crisis. We anticipate strong interest from private labs that support testing for travel, workplace and other environments, and we believe high-throughput Fluidigm technology and the extraction-free nature of the assay will be among key drivers in Europe. Furthermore, our assay features an integrated testing platform and a reliable supply chain that laboratories can combine with commonly available automation platforms."

Fluidigm continually conducts *in silico* analyses to determine the effectiveness of the Advanta Dx Assay design to detect SARS-CoV-2. To date, none of the published viral mutations meaningfully impact the regions of the viral genome targeted by the assay's primers and probes.

Intended Use

The Advanta™ Dx SARS-CoV-2 RT-PCR Assay is a reverse transcription (RT) and real-time polymerase chain reaction (PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in saliva from patients who are suspected of COVID-19.

Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Advanta Dx SARS-CoV-2 RT-PCR Assay is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures.

Other Fluidigm products are For Research Use Only. Not for use in diagnostic procedures.

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 introduction and delivery of the Advanta Dx SARS-CoV-2 RT-PCR Assay in Europe, anticipated pricing and distribution channels for the assay, features and benefits of the assay, the potential European market size for COVID-19 testing, and demand for the assay in Europe. 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; the possible loss of key employees, customers, or suppliers; 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 authorizations or approvals to use our products and technology for diagnostic testing purposes; potential changes in priorities or requirements for Emergency Use Authorizations or other regulatory authorizations or approvals; potential limitations of any Emergency Use Authorization or other regulatory authorizations or approvals; 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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