Fluidigm COVID-19 Community Connect Program Builds a Network of Testing Partners to Increase Access of Saliva-Based SARS-CoV-2 Testing for Communities

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SOUTH SAN FRANCISCO, Calif., Nov. 17, 2020 (GLOBE NEWSWIRE) -- Fluidigm Corporation (Nasdaq:FLDM), an innovative biotechnology tools provider with a vision to improve life through comprehensive health insight, today announced COVID-19 Community Connect, a program to link federal, state and local governmental entities, public health agencies, academic institutions, workforces, individuals and a network of high-complexity labs to deliver saliva-based COVID-19 testing.

As demand for noninvasive saliva-based COVID-19 testing increases, Fluidigm is serving as a hub to connect interested communities with testing providers.

“Since announcing our Emergency Use Authorization for saliva-based PCR testing in late August, we have seen tremendous interest in our testing technology,” said Chris Linthwaite, Fluidigm President and CEO. “We created the Community Connect program to organize a system for assessing needs, recruiting lab partners and building a service ecosystem for delivering timely results. This model is proving to be an effective and scalable way to get the greatest number of our saliva-based COVID-19 tests to critical populations in communities across the United States.

“We have seen healthy adoption and growing demand for saliva-based testing with strong new instrument placements in clinical labs and public health and academic medical centers,” continued Linthwaite. “With many of the inquiries we receive, the community seeking our saliva test does not have access to appropriate lab facilities. To address this need, we developed the Community Connect program to match demand with testing supply. One example of this partnership model is an award to a partner testing lab for testing services around the federal surge testing effort under the U.S. Department of Health and Human Services Community-Based Testing Site program.

“We have been building a network of partner labs for a number of weeks, and we welcome additional partners as well as general inquiries from groups seeking reliable, cost-effective and easy-to-administer tests.”

In late August, Fluidigm received Emergency Use Authorization from the U.S. Food and Drug Administration for the Advanta™ Dx SARS-CoV-2 RT-PCR Assay, an extraction-free saliva-based test to detect nucleic acid from the SARSCoV2 virus. The assay does not require collection via invasive nasopharyngeal swab. The company’s clinical study submitted to the FDA demonstrated 100 percent agreement between saliva results from the Advanta assay and results from paired nasopharyngeal samples tested with authorized assays.

As an example of the types of connections Fluidigm is creating, Phase2 Labs of Nashville, Tennessee, has adopted the Advanta assay to market COVID-19 testing services to corporate and governmental entities, nursing facilities and on-location film crews.

“Phase2 is honored to collaborate with Fluidigm and other trusted partners to provide critically needed testing capacity to a range of organizations relying on COVID-19 tests to make strategic decisions about safety,” said Steven E. Kress, co-founder and CEO of Phase2 Labs.

“The saliva-based approach offers a simple, accurate, pain-free option for PCR COVID-19 testing, and Phase2 can deliver results within 24 to 48 hours. Based in Nashville, we’re within close reach of half the U.S. population, enabling us to be vital community partners in making a meaningful difference in this health crisis.”

The Advanta Dx SARS-CoV-2 RT-PCR Assay on the high-throughput Fluidigm® Biomark™ HD system features an integrated testing platform and a reliable supply chain that CLIA laboratories can combine with commonly available automation platforms.

Development, commercialization and implementation of the Advanta Dx SARS-CoV-2 RT-PCR Assay are supported by a $34 million definitive contract with the National Institutes of Health under the agency’s Rapid Acceleration of Diagnostics (RADx) initiative. The RADx initiative fast-tracks development and commercialization of innovative technologies to significantly increase U.S. testing capacity for SARS-CoV-2.

The Fluidigm RADx project is supported by the NIH Rapid Acceleration of Diagnostics initiative and 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.

Learn more about COVID-19 Community Connect: go.fluidigm.com/community-connect

Intended Use
The 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 SARS-CoV-2 in saliva specimens collected without preservatives in a sterile container from individuals suspected of COVID-19 by their health care providers. Testing is limited to 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. Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in saliva specimens during the acute phase of infection. 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. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities. 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. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative

specimen type if clinically indicated. 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. The Advanta Dx SARS-CoV-2 RT-PCR Assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

The Advanta Dx SARS-CoV-2 RT-PCR Assay is for In Vitro Diagnostic Use. It is for Use Under Emergency Use Authorization Only. Rx Only. It has not been FDA cleared or approved. It has been authorized by FDA under an EUA for use by authorized laboratories. It has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. It 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. **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.

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.

About Phase2 Labs
Phase2 Labs, based in Nashville, Tenn., is the nation's first commercial molecular laboratory dedicated to the diagnostic management of acute and chronic respiratory diseases including COVID-19, ARDS, Chronic Obstructive Pulmonary Disease (COPD), moderate to severe asthma, interstitial lung disease, and cystic fibrosis. We employ our expertise in respiratory pathology to provide testing and measurement services for SARS-CoV-2. By taking a proactive approach to the research and analysis of COVID-19, we are building toward higher quality and better services for those who suffer long-term respiratory concerns. This further equips us in the contemporary research for the development of new pharmaceutical products. For more information, visit: www.phase2laboratories.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 potential impact of a Fluidigm program on U.S. COVID-19 testing availability and distribution of Fluidigm's Advanta Dx SARS-CoV-2 RT-PCR Assay. 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 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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