Fluidigm and Healthvana Partner to Offer COVID-19 Test Results Delivery through Innovative Digital Platform

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Patients Receive Results, Education and Next Steps on Their Mobile Phones to Prevent Further Spread of the Disease

SOUTH SAN FRANCISCO, Calif., Nov. 05, 2020 (GLOBE NEWSWIRE) -- Fluidigm Corporation (Nasdaq:FLDM), an innovative biotechnology tools provider with a vision to improve life through comprehensive health insight, today announced that it has partnered with Healthvana Inc., the nation's leading patient platform for delivering COVID-19 test results, to provide clinical laboratory customers utilizing the Fluidigm® saliva-based Advanta™ Dx SARS-CoV-2 RT-PCR Assay with the option to deliver test results faster via Healthvana’s mobile platform.

“We are witnessing record-breaking infection rates, and shortening the time for the result to get to the patient is paramount,” said Ramin Bastani, CEO of Healthvana. “On average, after clinical laboratories return COVID-19 test results, we have found that patients view their result within 30 minutes when Healthvana acts as the ‘last mile.”’

Healthvana’s patient-friendly mobile platform delivers test results directly to patients and is tailored to reduce anxiety through easy-to-understand test result information, education and next steps. Patients can access their health information in less than a minute, in multiple languages, and print or download it to show a negative COVID-19 test result before going to school or work or getting on a plane.

Healthvana has partnered with states, local governments, labs, employers and schools to deliver more than 3 million COVID-19 test results since April.

“Since the onset of the global health crisis, companies, universities, governmental entities and others have demonstrated an ability to pivot rapidly and innovate in ways that move us another step closer to effectively managing through this pandemic,” said Chris Linthwaite, President and CEO of Fluidigm. “This spirit of collaborative problem solving is evident in the patient-focused delivery platform developed by Healthvana, and Fluidigm is pleased to have the opportunity to offer this game-changing tool to our clinical laboratory customers. We believe that Healthvana’s delivery platform and our testing technology will be an extraordinarily effective combination.”

Fluidigm in late August received Emergency Use Authorization (EUA) 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 SARS-CoV-2 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 Dx SARS-CoV-2 RT-PCR Assay and results from paired nasopharyngeal samples tested with authorized assays.

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.

Intended Use

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 provider. Testing is limited to laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and that 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 positive 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, the Fluidigm logo, Advanta, Biomark, and CyTOF are trademarks and/or registered trademarks of Fluidigm Corporation in the United States and/or other countries. All other trademarks are the sole property of their respective owners.

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 Healthvana

Healthvana’s mission is to help eliminate COVID-19 using technology. Since 2015, the mobile-first patient portal has been rooted in empathy, enabling HIPAA-compliant test results to be easily and quickly distributed to patients. Healthvana gives patients the ability to access their own health results anytime, while providing cities, labs, health systems, employers, skilled nursing facilities, homeless shelters and schools the ability to reduce costs, manage patient communication and inspire informed action for better outcomes.

Los Angeles-based Healthvana focuses solely on anxiety-provoking health information, and serves as the largest patient communication platform for COVID-19 and HIV in the U.S. For more information, visit www.healthvana.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 anticipated benefits of a collaboration relating to communication of COVID-19 testing results from Fluidigm clinical laboratory customers to such customers’ patients. 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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