Key Regulatory Body in India Grants Commercial License for Fluidigm Saliva-Based Advanta Dx SARS-CoV-2 RT-PCR Assay

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Fluidigm Assay is Among First Saliva-Based COVID-19 Tests Licensed for Use by Designated Labs in India

SOUTH SAN FRANCISCO, Calif., Nov. 24, 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 the Central Drugs Standard Control Organisation (CDSCO) in India has licensed importation and commercial sale of the Fluidigm® Advanta™ Dx SARS-CoV-2 RT-PCR Assay in that country for COVID-19 testing. The CDSCO license was granted to Premas Life Sciences, a Delhi based life sciences distribution company.

In India, the CDSCO leads regulatory approval for vaccines, diagnostics, prophylactics, and therapeutics designed to prevent or treat diseases including COVID-19. The Fluidigm test is one of the first saliva-based tests for COVID-19 to be licensed in India. The license granted to Premas Life Sciences provides for the Fluidigm assay to be used to track positive cases of COVID-19 using laboratories designated/approved by the Indian Council of Medical Research or the relevant state or central government.

“Premas Life Sciences has a passion for delivering game-changing technologies across an array of research and diagnostic areas,” said Praveen Gupta, Managing Director of Premas Life Sciences. **“**Fluidigm’s much-needed noninvasive saliva-based test comes at a critical time in the pandemic, and we are pleased to be able to facilitate availability of the Advanta assay in India.”

India's reported coronavirus cases have surpassed 9 million, a total so far exceeded only by the United States.

“Since announcing our Emergency Use Authorization in the United States for saliva-based PCR testing, we have seen growing interest in our technology,” said Chris Linthwaite, Fluidigm President and CEO. “License to market our Advanta Dx SARS-CoV-2 RT-PCR Assay in the world’s second-most populous nation will enable an effective and scalable way to get noninvasive saliva-based testing across India as a possible second wave of infections approaches.

“We are now in discussions with potential customers, which include private testing labs as well as academic institutions and government medical centers. We are honored for the opportunity to advance the availability of noninvasive saliva-based COVID-19 testing in India at this critical time.”

The Fluidigm assay does not require collection via invasive nasopharyngeal swab. The company’s clinical study submitted to the U.S. Food and Drug Administration demonstrated 100 percent agreement between saliva results from the Advanta 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 can be combined with commonly available automation platforms.

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.

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 distribution of and demand for Fluidigm’s Advanta Dx SARS-CoV-2 RT-PCR Assay in India. 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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