Two COVID-19 Test Kits Distributed by Datametrex Granted FDA Emergency Use Authorization

A major milestone for Datametrex, two of the Covid-19 test kits they distribute receive FDA EUA approval

TORONTO, ONTARIO, CANADA, June 9, 2020 /EINPresswire.com/ -- Datametrex AI Limited (the "Company" or "Datametrex") (TSXV: DM, FSE: D4G, OTC: DTMXF) is pleased to announce that Seasun Biomaterial's 20 minute rapid Nucleic Acid test kit, AQ-TOP COVID-19 Rapid Detection Kit, has received authorization from the U.S. Food & Drug Administration ("FDA") registered under the Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices ("EUA").

"These test kits can expedite the process of testing by reducing testing times, aiding in an earlier detection of the virus, a more accurate prediction of the positive cases, and a decrease of the infection rate," said Marshall Gunter, CEO of the Company.

Additionally Datametrex would like to provide an update on the 1drop Inc. ("1drop") test kits. The 1copy™ COVID-19 qPCR Multi Kit has secured FDA authorization under the EUA. This is a nucleic test kit providing results in less than two hours that verifies the RdRp gene for SARS-CoV-2 with real-time qPCR kits via a nasopharyngeal swab and oropharyngeal swab, specifically targeting the E gene sequences of COVID-19.

So far, Datametrex has a total of three (3) test kits that are FDA approved under Coronavirus Disease 2019 (COVID-19) Emergency Use Authorization for Medical Devices ("EUA") available for sale. The approved test kits are 1copy™ COVID-19 qPCR Multi kit, Seasun U-TOP™ COVID 19 Detection Kit, and AQ-TOP COVID-19 Rapid Detection Kit.

"Having seen the urgent need for COVID-19 test kits, Datametrex is doing everything it can to help Canada combat COVID-19 and flatten the curve. In the meantime, having FDA under EUA approved test kits allow us to help our neighbours to the south and any Canadian company with operations in the US," says Marshall Gunter, CEO of the Company.

With regard to the FDA authorization: (1) this test has not been FDA cleared or approved; (2) this test has been authorized by the FDA only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and (3) 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.

The Company's ability to fulfill any purchase order for COVID-19 test kits is subject to the availability of inventory at the time of order. Due to the extraordinarily high demand for COVID-19 test, there is volatility in the supply chain and available supply may fluctuate on a daily basis. Datametrex anticipates that it will have little or no upfront costs associated with importing and selling these test kits.

About Seasun Biomaterials

Seasun Biomaterials Inc. (“Seasun”) of South Korea is an in vitro diagnostic company that develops molecular diagnostic platforms of infection diseases, cancer as well as genetic and epigenetic disorders. Developing and commercializing innovative real-time PCR-based diagnostic platforms through the development of our proprietary technologies to provide more advanced molecular diagnostic services. Additional information on Seasun is available at www.seasunbio.com

About 1drop Inc.

1drop Inc. aims to provide a solution to manage health with a drop of fluid. It has the key technologies for becoming a global leading company in the field of smart health care. 1copy™ COVID-19 qPCR Multi Kit can reduce the risk of asymptomatic and latent infection of COVID-19 by a single virus level limit of detection. It is located in South Korea and is a medical technology spin-off from Samsung Electronic’s C-Lab program. The C-Lab is an internal incubation program within Samsung that first started in 2012 to help inspire a more creative company culture. 1drop already has more than five products approved in Europe in the past 18 months under the CE marking certification. The team has been working around the clock to identify and source high quality test kits from South Korea for Canada. Additional information on 1drop Inc. is available at www.1drop.co.kr

About Food and Drug Administration EUA

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that

circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.

About Datametrex

Datametrex AI Limited is a technology focused company with exposure to Artificial Intelligence and Machine Learning through its wholly owned subsidiary, Nexalogy (www.nexalogy.com). Datametrex's mission is to provide tools that support companies in fulfilling their operational goals, including Health and Safety, with predictive and preventive technologies. By working with companies to set a new standard of protocols through Artificial Intelligence and health diagnostics, the Company provides progressive solutions to support the supply chain. Additional information on Datametrex is available at www.datametrex.com.

Marshall Gunter
Datametrex AI Limited
+1 514-295-2300
email us here