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DeepVerge PLC
("DeepVerge" or "Company")

Microtox® BT Evaluation of SARS-CoV-2 from breath test with Clinical Samples

Average virus breath condensate digital signal 9x larger than control on nano-chip

DeepVerge (LSE:DVRG.L), the environmental and life science AI company, announces initial data for ongoing Phase III clinical studies on the detection of SARS-CoV-2 on breath samples and identification of confirmed COVID19 positive patients .

Since Q3 2020, DeepVerge scientists have been working under laboratory conditions with the Spike Protein ("S-Protein") of SARS-CoV-2 on the SARS-CoV-2 virus inside the Containment Level 3 ("CL3") laboratories at the University of Aberdeen. In these studies, they have detected and identified the virus S-Protein in quantities at 40 femtogramⁱ per millilitre ("Fg/mL") at close to 100% sensitivity and specificity on DeepVerge's Microtox® BTⁱ nano-optofluidic chip.

In addition, under the clinical trial supervision of the Royal College of Surgeons, Ireland, 40 subjects, 16 of which were independently confirmed as COVID19 positive with PCRⁱⁱⁱ tests, provided breath samples that were tested on the Microtox® BT nano-optofluidic chip surface with Affimer® reagents ("Avacta Group")^{iv} and Optimers ("Aptamer Group")^v together the ("Binding Agents").

The breath samples detected binding on the nano-optofluidic chip with a secondary antibody to the Spike Protein which was initially selected for the isolated spike protein work. Detection of the live virus was confirmed indicating 9 times increase in the digital spectrum signal on the Microtox® BT when compared to controls of nano-optofluidic chips with binding agent; and 19 times increase in signal with nano-optofluidic chips without binding agents. Additional digital background noise was indicated due to the non-specific binding of the antibody. Further data is required to confirm the same high sensitivity and specificity is achieved on breath test clinical trials which are underway.

Gerard Brandon CEO of DeepVerge plc commented:

"DeepVerge scientists have transformed its AI based water contamination detection system, developed over five years for e.coli, into the breath condensate Microtox® BT unit. Having successfully completed Phase I testing on the Spike Protein and Phase II studies with SARS-CoV-2 virus in the safety of CL3 laboratories, the initial results of Phase III real-world clinical studies in COVID19 patients have reached a major milestone with the demonstration that our Microtox® BT can deliver results in under 60 seconds from breath samples."

"The requirement for the UK Target Product Profile ("TPP") Rapid Breath Test requires 150 confirmed positive samples and 250 confirmed negative samples. Additional supervised breath test clinical trials from a larger group is expected to provide sufficient data to meet the desired and acceptable criteria in the TPP to roll out the COVID19 and other pathogen breath tests later this year."

Tracking progress of the stages of the infection

The Company notes the publication^{vi} by UK Medicines & Healthcare products Regulatory Agency ("MHRA") of the "Target Product Profile Rapid Breath Tests for the direct and indirect detection of SARS-CoV-2". Microtox® BT satisfies many of the "Desired" and "Acceptable" criteria within the document.

Subject to the limitations of the Binding Agents' ability to capture the virus, the Microtox® BT breath test does or does not see the virus, eliminating false positives and enabling each test the potential to predict the following conditions:

- Asymptomatic and non-infectious,
- Asymptomatic and infectious,
- Symptomatic and infectious, and
- Symptomatic and non-infectious



Point-of-Care makes it possible to track and trace the progress of the stages of any infection, including COVID19, subject to the type of pathogen (bacteria, virus, fungi or parasite) or biomarker of a disease being targeted by the Binding Agents.

AI algorithms are designed to assess the risk of steric hindrance, in the case of SARS-CoV-2, by the capture of one S-Protein and one viral particle, blocking the binding of other viral particles in the immediate vicinity.

With ability to detect and identify the binding of individual S-Proteins at Fg/mL, the viral particle can be calculated to generate a bigger shift in the laser signal. Using AI, this relates back in Fg/mL of S-Proteins which indicates a viral load for each test subject.

The joint development program of work on the PBM-HALE™ breath condensate device from PulmoBioMed is ongoing using multiplex bio-marker binding agents to analyse breath for 40 other diseases which include cancer, neurodegenerative, respiratory and metabolic conditions.

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About DeepVerge plc (www.deepverge.com)

DeepVerge is an environmental and life science group of companies that develops and applies AI and IoT technology to analytical instruments for the analysis and identification of bacteria, virus and toxins. Utilising artificial intelligent data analytics to scientifically prove the impact of skincare product claims on skin microbiome for most of the top 20 global cosmetic company clients and remotely detect and identify in real-time, dangerous pathogens in wastewater treatment plants, drinking water, rivers, lakes and reservoirs.

ⁱ **1 Femtogram** is 1.0E-18 or exactly 0.000000000000000001 kilograms (SI unit). As per the prefix a gram is a thousandth of a kilogram.

ⁱⁱ **Microtox® BT** is a rapid diagnostic human breath condensate test that detects and identifies a range of infectious viruses and bacteria which include SARS-CoV-2, on a single chip, using AI, in real-time with the ability monitor disease progression.

ⁱⁱⁱ **PCR** – Polymerase Chain Reaction

^{iv} **Avacta Group plc (www.avacta.com)**

Avacta Group is developing novel cancer immunotherapies and powerful diagnostics based on its two proprietary platforms - Affimer® biologics and pre|CISION™ tumour targeted chemotherapies.

The Affimer platform is an alternative to antibodies derived from a small human protein. Despite their shortcomings, antibodies currently dominate markets, such as diagnostics and therapeutics, worth in excess of \$100bn. Affimer technology has been designed to address many of these negative performance issues, principally: the time taken to generate new antibodies and the reliance on an animal's immune response; poor specificity in many cases; their large size, complexity and high cost of manufacture.

^v **Aptamer Group Ltd. (www.aptamergroup.com)**

Aptamer Group is a world-leading provider of bespoke nucleic acid aptamer selection and development services, working with partners across the pharmaceutical, biotechnology and diagnostic sectors.

Optimers are optimized aptamer reagents. Based on oligonucleotide molecules Optimers can bind specifically to a target molecule to act as an antibody alternative. Their ability to fold into distinct secondary or tertiary structures gives them high affinity and specific binding toward targets of interest, from small molecules to cells. They are emerging as promising alternatives in a range of applications.

^{vi} **Target Product Profile** “*Rapid Breath Tests for the direct and indirect detection of SARS-CoV-2*”
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/966283/Breath_TPP_Final_version_v1.0.pdf

The intended use of detection tests that match these profiles (or one that does not yet meet the specifications but looks promising) is to aid in the triage of people with a current SARS-CoV-2 infection by detection of SARS-CoV-2 in human samples. Ideally, products should be designed to achieve as many of the desired characteristics as are feasible, while still satisfying the minimal criteria for all defined features. However, a test that does not yet meet all these profiles may still have a role in supporting the UK testing strategy and can be considered on a case by case basis.