

genedrive plc ("genedrive" or the "Company")

Point-of-Care solution to detect SARS-CoV-2 virus in saliva

Development update

genedrive plc (LSE: GDR), the near patient molecular diagnostics company, announces it has completed the assay design for the Company's Point-of-Care ("POC") solution for COVID-19 testing and is now generating very promising analytical data aligned to market requirements.

The Genedrive[®] SARS-CoV-2 Kit is being designed to detect SARS-CoV-2, the virus causing COVID-19, amplified directly from a saliva sample without the need to extract viral RNA. This expands the potential use areas of the product and importantly, allows for rapid testing to be performed while a patient is present. When running on the Genedrive[®] POC device the chemistry is detecting a positive SAR-CoV-2 sample in approximately 15 minutes, with fully negative samples taking just over 20 minutes to resolve. The limit of detection is in line with the UK's MHRA Target Product Profile sensitivity requirements.

The Genedrive SARS-CoV-2 POC Kit follows a similar workflow that has already been validated in the Company's Genedrive[®] HCV-ID Kit which received WHO pre-qualification earlier this year.

The Company is targeting the end of the calendar year for completion of preliminary product evaluations, with full release of the final CE Marked system in Q1 2021 allowing for thorough clinical testing requirements. Additionally, the Company is working to progress to a version 2 of the product, which would accept a similar freeze-dried PCR bead format previously developed for the high throughput Genedrive[®] 96 SARS-CoV-2 Kit. This will allow for lower production costs and highly scalable manufacturing capacity.

David Budd, Chief Executive Officer of genedrive plc, said: "Rapid testing for current infection is a cornerstone to any track and trace programme, to quickly accessing current infection, to limiting infection, and to giving assurance to people concerned about their status. We believe the Genedrive® POC solution can contribute significantly to the ongoing management of this global health crisis."

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About genedrive plc (<u>http://www.genedriveplc.com</u>)

genedrive plc is a molecular diagnostics company developing and commercialising a low cost, rapid, versatile, simple to use and robust point of need molecular diagnostics platform for the diagnosis of infectious diseases and for use in patient stratification (genotyping), pathogen detection and other indications. The Company has assays on market for the detection of HCV, certain military biological targets, and has tests in development for tuberculosis (mTB). The Company recently announced the development of a high throughput SARS-CoV-2 assay and a Genedrive[®] Point of Care version of the assay, both based on Genedrive[®] PCR chemistry.