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

Manufacturing milestones achieved for SARS-CoV-2 test

Genedrive® 96 SARS-CoV-2 kit passes critical technical development milestones in Cytiva manufacturing process

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, announces it has completed the last significant manufacturing milestone in the co-development of the Genedrive® 96 SARS-CoV-2 kit with Cytiva. The PCR-based test has completed its pilot manufacturing runs and yielded high performing multiplexed assays for COVID-19 testing. The overall project plan currently remains on track and the company is targeting CE marking in approximately 3 weeks' time.

The Genedrive® 96 SARS-CoV-2 test is one of two assay programmes the Company is developing following an announcement made on 25 March 2020, with a genedrive point-of-care assay due later in the calendar year.

The Genedrive® 96 SARS-CoV-2 assay combines genedrive's PCR chemistry integrated with Cytiva's LyoStable® stabilisation technology. The combination delivers several key competitive advantages to the genedrive test compared to the liquid, kit-based assays already on market. The Genedrive® 96 SARS-CoV2-test is a final format test which only requires the addition of patient sample, with no other user preparation required. Integrated controls within each test give confidence to the user that the input sample is of good quality, and the integrity of each reaction mix is confirmed with another internal standard. The temperature-stable nature of lyophilisation technology means that the test can be transported globally without the need for refrigeration, which will support global product distribution.

David Budd, Chief Executive Officer of genedrive plc, says: *"We are very pleased to have passed these technical milestones and with CE marking planned we will offer our novel high throughput test in the near future. Users will be able to adopt a COVID19 testing solution with unique assay features. The team here at genedrive has been working in close cooperation with the Cytiva team – and both have excelled in the development of a complex assay, while maintaining a firm focus on quality and performance; we remain confident that this assay will make a significant contribution to the testing market."*

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About genedrive plc (http://www.genedriveplc.com)
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 Genedrive® mt-RNR1-ID kit has received CE-IVD Certification and will be launched into Europe and other markets following full evaluation by the UK National Health Service. 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 the high throughput SARS-CoV-2 assay, based on Genedrive PCR chemistry.

About Cytiva

Cytiva is a 3.3 billion USD global life sciences leader with nearly 7,000 associates operating in 40 countries dedicated to advancing and accelerating therapeutics. As a trusted partner to customers that range in scale and scope, Cytiva brings speed, efficiency and capacity to research and manufacturing workflows, enabling the development, manufacture and delivery of transformative medicines to patients. Visit www.cytiva.com for more.