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

Point-of-care Genedrive® COV19-ID submitted for CE-IVD certification

Sets new benchmark in speed, accuracy and ease of use

genedrive plc (LSE: GDR), the near patient molecular diagnostics company, announces that it has submitted its new rapid Point of Care molecular test for SARS-CoV-2 detection for CE-IVD certification under the European Communities Council Directive 98/79. The Genedrive® COV19-ID kit offers a step change in rapid molecular testing, delivering positive results as quickly as 7.5 minutes and negative results at 17 minutes.

Following self-certification, the Genedrive® COV19-ID Kit has been passed to genedrive's Authorised Representative for formal registration, a process expected to take ten working days to complete, following which the product can be made available commercially in the European Union. In parallel, the product is being provided for review and evaluation to a range of potential commercial partners who have actively expressed interest in the product.

The Genedrive® COV19-ID Kit is based on the rapid molecular technique Reverse-Transcription Loop Mediated Isothermal Amplification (RT-LAMP). The test has an analytical Limit of Detection (LoD) of 52 copies per test. It is performed directly from a nasal swab using the Genedrive® Point of Care platform. The assay targets the ORF1ab and N genes of the SARS-CoV-2 genome, adding robustness against emerging SARS-CoV-2 variants which generally impact assays targeted against the S-gene (Spike protein). In the case of the new B.1.1.529 South African variant ("Omicron"), while less than 100 genetic sequences had been made publicly available at the time of CE submission, none of them had mutations affecting the assay design of the Genedrive® COV19-ID Kit.

Sensitivity and specificity was 98.2% and 98.9% respectively in a clinical validation cohort of 149 samples (58 positives at greater than 500 copies per ml) which were referenced against the Thermo Fisher TaqPath COVID-19 RT-PCR test. The Genedrive® COV19-ID molecular test offers several orders of magnitude improvement in sensitivity compared to antigen lateral flow devices, which range widely in sensitivity, from 0.1 million copies per ml analytically[1] and from >1 million copies per ml under clinical evaluation[2]. The clinical cohort included five confirmed SARS-COV2 Delta variants,

which were all detected by the Genedrive® COV19-ID test. The sensitivity and specificity of the assay on the entire cohort met the current requirements of the UK's MHRA Target Product Profile for a SARS-CoV-2 Point of Care molecular diagnostic test.

Information about the Genedrive® instrument and the new Genedrive® COV19-ID Kit can be found at http://www.genedrive.com/assays/cov19-id-assay.php

The Company's initial commercial focus is the European Union, utilising the regulatory clearance of CE marking, and will be followed by the UK. The registration processes in the UK require a larger sample set than for CE marking and submission under CTDA legislation. The Company is actively recruiting patient samples for these expanded requirements, which is proceeding well.

David Budd, CEO of genedrive plc, said: *"I am delighted to say that development work from the Company has resulted in designing and delivering a product with excellent performance specifications and a speed to result that is a new benchmark. The new Genedrive® COV19-ID Kit combines the speed and ease of lateral flow testing with molecular level accuracy in a low cost and portable device. We are now able to progress the commercial evaluations of the product to selected partners and given its performance in our studies, we believe there remain substantial market opportunities that can be targeted. As recent news of the Omicron variant demonstrates, COVID-19 remains a significant issue in global health and thus rapid and accurate testing will remain a critical tool in managing the spread of the virus."*

The Company is seeking commercial partners in some specific EU countries. Potential partners can register their interest via info@genedrive.com

1 - Cubas Atienzar A. et al., Scientific Reports (2021) 11:18313
2 - García-Fiñana, A. et al. BMJ 2021;374:n1637 | doi: 10.1136/bmj.n1637

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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 Company has assays on market for the detection of HCV and certain military biological targets. The Company recently released a high throughput SARS-CoV-2 assay and has a point of care version of the SARS-Cov-2 test due on market during 2021.

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