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

Genedrive® COVID-19 Point of Care device update

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, provides an update on the development of its Genedrive® COV19-ID Kit, a rapid Point of Care (PoC) molecular test for SARS-CoV-2 detection, designed for the Company's Genedrive® instrument.

The Company has been developing a new, best-in-class PoC molecular workflow and assay for more than 9 months. The Company is pleased to release the product's current performance specifications as it moves towards the stages of formal clinical qualification and regulatory filing. While acknowledging the longer than anticipated development time, the Company has overcome significant technical hurdles and also further improved performance specifications alongside evolving marketplace requirements. Key specifications of sensitivity, specificity, speed, ease of use, and scalability have all been improved or addressed.

The Genedrive® COV19-ID Kit detects the presence of SARS-CoV-2 virus in a nasal swab. The product has been designed to provide an ease of use appropriate for people inexperienced in molecular testing. Positive samples are detected as quickly as 9-10 minutes, with a negative result reported after 20 minutes if no signal is detected.

In contrast to many competitor products, the test targets two genes of the SARS-CoV-2 genome, and is shown to be inclusive of all current Variants of Concern (VoCs), including the Delta variant. The intent of a two-gene design is to provide additional robustness to new emerging VoCs in the future. The specificity of the test during design verification (30 positive and 30 negative contrived clinical samples*) was 100%, with a PCR comparable limit of detection of 10-20 copies per reaction.

The testing procedure does not require extraction of the virus from the patient's sample. The Company has developed a proprietary lysis buffer that is used to resuspend patient swab material, while providing biosafety to users. Exact quantification of biosafety is currently being assessed in an independent UK Public Health England laboratory. A fully biosafe process would present additional or novel opportunities and use-cases for PoC COVID-19 testing.

The simple, 4-step workflow uses an 'eye-dropper' liquid transfer process familiar from lateral flow testing, and makes the system appropriate for use by those without previous molecular experience. The ease of use of the Genedrive COV19-ID test is demonstrated at:

https://www.genedrive.com/assays/in-development-covid19-id.php

Full clinical validation on patient specimens is required for regulatory registration and/or other emergency listings. The Company is optimistic that this can be completed successfully and is targeting CE marking at the end of September / early October, with prospective patient sample collection already underway. The Company is targeting initial product launch in Europe.

* *Natural human samples spiked with heat inactivated virus at various clinically relevant viral loads*

David Budd, CEO of genedrive plc, said: *"We are pleased to have achieve significant milestones in the development of our Genedrive® COV19-ID Kit and we have a product in which we are extremely proud. Once formally validated, we believe we can make commercial in-roads by expanding the opportunities to get a quick and sensitive molecular test for SARS-CoV-2. The product to date demonstrates a suite of features that have significant competitive advantage: simplicity of workflow, an extraction free procedure, biosafety for the user, multi-gene targeting, rapid time to result, high sensitivity, and cost effectivness. Whether in highly vaccinated countries or not, COVID-19 is*

likely to be an illness that we live with in the long term, necessitating rapid and accurate testing for infection in a wide range of environments, including outside of healthcare settings. Our commercial activities are currently focused on engaging the appropriate commercial partners to be in place in the autumn as the levels of infection undoubtedly rise in many geographies."

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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, certain military biological targets, and has tests in development for tuberculosis (mTB). The Company recently released a high throughput SARS-CoV-2 assay.