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

Genedrive COVID-19 PCR test approved by Indian regulator

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, announces that the Genedrive® 96 SARS-CoV-2 Kit has been formally approved by the Indian Council of Medical Research ("ICMR"). The Genedrive® 96 SARS-CoV-2 Kit achieved 100% sensitivity and 100% specificity in the performance evaluation conducted by the ICMR. The Company will now commence commercial activities in India through its existing distributor Divoc Health and will also be seeking additional routes to the market.

David Budd, CEO of genedrive plc, said: *"We are very happy to achieve formal registration of our COVID PCR tests in India. Although the process took longer than anticipated, the performance data is excellent and will support the commercial process and customer engagement. Formal product approval is an excellent testament to our technology."*

The Genedrive® 96 SARS-CoV-2 Kit is a novel Polymerase Chain Reaction ("PCR") assay designed to detect active SARS-CoV-2 infection in COVID-19 patients. genedrive's proprietary "ready-to-go" solid PCR bead format eliminates the need for reagent preparation or cold temperature storage, making it a preferable solution for high temperature countries such as India. The format streamlines laboratory workflow, allowing a patient sample to be mixed with a single bead and then tested on a variety of third-party RT-PCR platforms. The test is validated for use on certain Biorad, ThermoFisher, and Roche PCR platforms.

Given the escalating infection rate in the country, this week India began to allow the import of certain COVID test kits with foreign registrations, including CE-Marking, without the need for ICMR approval. The country has also introduced pricing controls into the public market, setting a dynamic that does favour the provision of "basic" tests. The Company believes however that formal performance evaluation data and ICMR approval will contribute positively to commercial efforts and premium products such as gendrive's can play a part in the need for COVID-19 testing.

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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 and has in development a Genedrive® Point of Care version of the assay, both based on Genedrive® chemistry.