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genedrive plc (“genedrive” or the “Company”)

Genedrive® HCV ID Kit received CE-IVD Certification

Hepatitis C assay provides decentralised molecular testing to support the identification of patients that could benefit from direct acting antiviral therapy

genedrive plc (LSE:GDR), the molecular diagnostics company, today announces that the Company has achieved CE certification under the EU Medical Devices Directive for its Genedrive® HCV ID Kit, a qualitative molecular assay for Hepatitis C (HCV). CE marking allows for introduction of the assay into Europe as well as low and middle income countries that accept CE certification under their national regulations. In other countries, CE marking can be a necessary prerequisite to begin local registration processes and is an important endorsement for potential distribution partners.

David Budd, CEO of genedrive plc, said: "It is an exciting achievement to be the first company to launch a molecular HCV test designed to be used in smaller hospital laboratories and clinics. CE Marking will allow us to engage with many of the countries where HCV is an endemic healthcare issue. The combination of national screening programs, the availability of cost effective treatment, and consequently a growing demand for molecular diagnostics is an area we can contribute to in a meaningful way. Treatment with pan-genotypic direct acting antivirals can be initiated immediately following a positive HCV result using the Genedrive HCV assay allowing for effective linkage to care, and reducing patient loss during the follow up."

The Genedrive® HCV assay is performed on the Genedrive® instrument, an innovative and affordable system providing molecular diagnostics at the point of need. The proprietary assay is performed directly from a small, 25ul plasma sample and does not require a separate viral nucleic acid extraction process. The assay provides results within 90 minutes from lyophilised PCR reagents packaged into a single-use, disposable cartridge. Performance evaluation studies to support CE marking of the assay (Institut Pasteur, Paris & Queens Medical Centre, Nottingham) demonstrated sensitivity and specificity fulfilling the requirements published by FIND, the Foundation for Innovation in New Diagnostics.

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Notes to Editors

About genedrive plc

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.

Further details can be found at: www.genedriveplc.com and www.genedrive.com

About Hepatitis C

Hepatitis C is an international public health challenge, comparable to other major communicable diseases, including HIV, tuberculosis and malaria. It is estimated that 150–200 million people, or approximately 3% of the world's population, are living with chronic hepatitis C, and more than 350,000 people die yearly from hepatitis C related diseases. In 2016, WHO published the first global health sector strategy on Hepatitis with a goal of eliminating viral hepatitis as a major public health threat by 2030. New oral, well-tolerated treatment regimens can achieve cure rates of over 90% however access to rapid, inexpensive and accurate diagnostics are a critical bottleneck that must be addressed to eradicate Hepatitis C.