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

Genedrive® HCV Assay submitted for CE IVD Certification

Significant Step in Commercialisation of HCV Assay for Decentralised Use in Resource Limited Settings

genedrive plc, the near patient molecular diagnostics company, today announces submission of its Genedrive® HCV ID Kit for CE IVD certification under the EU Medical Devices Directive. Receipt of CE IVD certification will allow commercialisation of the product within the EU and in resource limited countries in the rest of the world that accept CE certification under their national regulations. Where local registration is required, CE marking is often a prerequisite.

The application for CE Marking is supported by excellent performance data in recent clinical validation studies. These studies, performed at Institut Pasteur, Paris, and Queen’s Medical Centre, Nottingham, show that the Genedrive® HCV ID Kit sensitivity, specificity, and limit of detection meet the Target Product Profile specifications for decentralised use in resource limited setting as outlined by the Foundation for Innovation in Diagnostics (FIND).

The qualitative molecular HCV assay allows for decentralised testing of Hepatitis C (HCV), providing results within 90 minutes direct from a small plasma sample (25ul). The Genedrive® HCV assay demonstrated a sensitivity of greater than 99% and specificity of 100% over the 955 sample cohort when comparing the assay to the Abbott Molecular RealTime HCV Viral Load test. The assay is performed on the Genedrive® platform, a portable molecular diagnostics system designed for use at the point of need.

Professor William Irving, Professor of Virology at Queens Medical Centre Nottingham, and clinical virology expert in hepatitis diagnosis, management and pathogenesis, was the lead investigator at the UK site involved with the clinical performance assessment of the Genedrive® HCV assay.

Professor Irving said, “The diagnostic and treatment landscape for HCV has changed rapidly in recent years, and with the introduction of direct acting antivirals, there is a real opportunity to tackle the global burden of Hepatitis C. Accurate, decentralised diagnostics, like Genedrive® HCV, promise to be a big step forward in addressing the challenges associated with identifying and diagnosing those living with HCV infection and to give them access to this new and effective therapy.”

David Budd, Chief Executive Officer of genedrive plc said, “Application for CE Marking for the Genedrive® HCV assay is a significant step in our development of a decentralised and qualitative molecular HCV test, which could be the first of its kind to market. As we go through this process, we look forward to updating the market with our commercial partnership arrangements and target geographies for initial product introductions.”

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Notes to Editors

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® platform and MTB/RIF test have been launched in India and a Genedrive® HCV test has been successfully assessed by the Institut Pasteur, Paris.

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.