



For release: [7th March 2017]

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

Successful Clinical Results for Genedrive[®] HCV Assay

External Validation Studies Show Sensitivity of greater than 99% and Specificity of 100% for Hepatitis C Assay Designed for Decentralised Use in Resource Limited Settings

genedrive plc, the near patient molecular diagnostics company, today announces that it has successfully completed clinical validation studies to support a submission for CE regulatory approval of its Genedrive[®] HCV ID Kit.

The studies, performed at Institut Pasteur, Paris, and Queen’s Medical Centre, Nottingham, demonstrated an overall sensitivity of greater than 99% and specificity of 100% over a 955 sample cohort, comparing the test to the Abbott Molecular RealTime HCV Viral Load Assay. The Genedrive[®] HCV ID Kit sensitivity, specificity, and limit of detection meet the Target Product Profile specifications for decentralised use in resource limited settings, as outlined by the Foundation for Innovation in Diagnostics (FIND). The validation studies were supported by the European Commission FP7 PoC-HCV programme.

The HCV test is performed on the Company’s Genedrive[®] portable molecular diagnostics platform, designed for use at the point of need. The assay uses only a small amount of human plasma (25ul), eliminating the need for a separate RNA viral extraction process, and yields results within 90 minutes.

“Recently approved direct acting antiviral therapies have revolutionised therapeutic options for treating HCV patients, however the challenge remains to identify infected persons, many of whom are living in geographic regions that lack access to state-of-the-art diagnostics,” **said Dr Darragh Duffy of the Institut Pasteur**. “The Genedrive[®] HCV ID Kit is a rapid and simple to use point of need test that would enable real-time treatment and management of chronic HCV patients in decentralised settings.”

“We are very pleased with the performance of the assay’s sensitivity, specificity and speed. This presents the Genedrive[®] HCV test with the opportunity to be the first to market as a decentralised, qualitative, molecular HCV test,” **said David Budd, Chief Executive Officer of genedrive plc**. “WHO HCV testing guidelines recommend the initiation of treatment with direct acting antiviral agents, following a qualitative or quantitative HCV molecular test. The Genedrive[®] HCV ID Kit is well placed to support the goal of increasing access to HCV diagnostics in decentralised laboratories in resource limited settings.”

The Company anticipates submission for CE certification under the EU Medical Devices Directive for Genedrive[®] HCV ID Kit by the end of March 2017. CE certification is a key step toward product commercialisation later this year.

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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. The Genedrive® platform and MTB/RIF assay has been launched in India.

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.

Further details on the PoC-HCV project can be found at <http://www.poc-hcv.eu/index.php>