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

Publication of Genedrive® Hepatitis C Test Performance Data in BMJ Gut

Studies in UK, France and South Africa showed >98% sensitivity and 100% specificity across all major HCV genotypes

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, today announces the publication of analytical performance and field evaluation studies of its Genedrive® HCV ID Kit in Europe and Africa in the prestigious *BMJ Gut*, a leading international journal in gastroenterology and hepatology¹.

The paper is available to view online at: <http://gut.bmj.com/content/gutjnl/early/2018/04/03/gutjnl-2017-315783.full.pdf>

The publication reports on assay performance data generated and used for Genedrive®’s CE-IVD certification, including analytical performance data as well as field performance evaluation. Field performance evaluation studies were performed in Europe by the Institut Pasteur, Paris and Queen’s Medical Centre, Nottingham, and in Johannesburg, South Africa by Lancet Laboratories, a commercial clinical facility providing testing services for patients from South Saharan countries.

Pan-genotype performance, with excellent exclusivity for non-HCV pathogens and sensitivity of greater than 98% and specificity of 100% in samples of European and African origin (including South Africa, Kenya, Ghana, Nigeria, Uganda is reported), was observed. The test was validated in a real clinical setting in a resource-limited country.

The paper concluded that Genedrive® HCV ID Kit was a rapid, simple, portable and accurate near patient molecular test for HCV, with sensitivity and specificity that fulfils the recent FIND/WHO target Product Profile for HCV decentralised testing in low income and middle-income countries.

David Budd, Chief Executive Officer of genedrive plc., commented: “This high impact peer reviewed publication provides further validation of the performance of our Genedrive® HCV ID assay. We are first to market with a decentralised qualitative molecular HCV test for use at point of need and believe we have the potential to positively impact the continuum of care from screening to cure by supporting real-time treatment decisions.”

Dr Darragh Duffy of the Institut Pasteur, said: “Whilst direct acting antiviral therapies have revolutionised therapeutic options for treating HCV patients, the challenge remains to identify people infected with the virus, many of whom are living in geographic regions that lack access to state-of-the-art diagnostics. We are proud to have partnered with genedrive through our EU Framework 7 funded POC-HCV consortium to aid realisation of this rapid point of need test that enables real-time treatment

¹ Libre A, Shimakawa Y, Mottez E, et al. Gut Epub ahead of print: doi:10.1136/gutjnl-2017-315783

and management of chronic HCV patients in decentralised settings, and to have seen our work published in this prestigious journal following extensive peer review.”

genedrive has distribution agreements with subsidiaries of Sysmex Corporation for the distribution of the Genedrive® platform in the EMEA and SE Asia (ex India), and with ARKRAY Healthcare pvt Ltd for the distribution of the Genedrive® HCV ID Kit and Genedrive® platform in India. genedrive recently announced first commercial sales of instruments and assays in Africa and Asia Pacific, excluding India.

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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® HCV-ID test has received CE-IVD Certification and has been launched in Africa and Asia Pacific. genedrive has distribution agreements with subsidiaries of Sysmex Corporation for the distribution of the Genedrive® platform in the EMEA and SE Asia (ex India), and with ARKRAY Healthcare pvt Ltd for the distribution of the Genedrive® HCV ID Kit and Genedrive® platform 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.