



GENEDRIVE PARTNERS WITH FIND TO EVALUATE A MOLECULAR DIAGNOSTIC KIT FOR HEPATITIS C VIRUS IN DECENTRALISED SETTINGS

- Evaluation studies of the Genedrive[®] HCV ID Kit will take place in Cameroon and Georgia
- Assay designed for use in low-resource settings, delivering results in 90 minutes

Manchester, U.K. and Geneva, Switzerland – 8 August 2018 – genedrive plc, a near patient molecular diagnostics company, and the Foundation for Innovation of New Diagnostics (FIND), announced today a study agreement for the performance evaluation of genedrive plc's hepatitis C virus (HCV) Genedrive[®] HCV ID Kit. The Genedrive[®] HCV ID Kit is a qualitative HCV diagnostic assay, performed on the company's portable molecular diagnostics platform, Genedrive[®]. The assay is designed for use in low-resource settings, and delivers results in 90 minutes.

Under today's agreement, FIND will lead evaluation studies in Cameroon and Georgia between September 2018 and May 2019. These studies are designed to confirm the diagnostic accuracy of Genedrive[®] HCV ID across diverse genotypes, as well as to assess usability in the intended market setting. genedrive plc will provide product in-kind to support the study.

"We are appreciative of the support of FIND in leading these studies," said David Budd, CEO of genedrive plc. "Positive outcomes should further facilitate our commercialisation activities in these regions, as well as providing important clinical field data that others look to as they decide to implement Genedrive[®] in their own specific settings."

FIND's evaluations of Genedrive[®] HCV ID Kit will feed into the organization's broader HCV efforts. FIND is the lead partner on a multi-year, multi-country HCV project funded by Unitaid to support the development of simple HCV diagnostic tools for use at the point of care, which can be made widely available to those who need them.

"These studies are a perfect fit with our ongoing efforts to improve the options for affordable, easy-touse HCV diagnostics," said Francesco Marinucci, Head of HCV and HIV at FIND. "We look forward to the results and to ongoing collaboration with genedrive plc."

The World Health Organization estimated that 71 million people had chronic HCV infections in 2015. If left untreated, HCV can cause serious, lifelong illness or death due to liver cirrhosis. Levels of HCV coinfection with HIV and tuberculosis (TB) are high, meaning failure to address HCV will affect efforts to control both TB and HIV. The global health sector aims to eliminate viral hepatitis as a public health threat by 2030. Given advances in HCV drug development, treatment options have become easier and more affordable. However, similar progress has not been made in HCV diagnostic development. There is a critical lack of easy-to-use, affordable tools for diagnosis at the point of care – an estimated 80% of people living with HCV are not diagnosed.¹

FIND's contribution to this initiative is supported by Unitaid.

About genedrive plc

¹ WHO global hepatis report 2017, <u>http://apps.who.int/iris/bitstream/10665/255016/1/9789241565455-eng.pdf?ua=1</u>

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 Kit 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 Asia Pacific regions, and with Arkray Pvt Ltd in India. Genedrive® mTB assay is in development. Further details can be found at: www.genedriveplc.com and www.genedrive.com

About FIND

FIND was established in 2003 as a global non-profit dedicated to accelerating the development, evaluation and delivery of highquality, affordable diagnostic tests for poverty-related diseases, now including malaria, tuberculosis, HIV/AIDS, sleeping sickness, hepatitis C, leishmaniasis, Chagas disease, Buruli ulcer, non-malarial fever and diseases with outbreak potential, such as Ebola. FIND has partnered in the delivery of 20 new diagnostic tools and created an enabling environment for numerous others through the provision of specimen banks, reagent development and better market visibility. FIND also supports better access to new diagnostics through implementation, quality assurance and lab strengthening work. FIND has nearly 200 partners globally, including research institutes and laboratories, health ministries and national disease control programmes, commercial partners, bilateral and multilateral organizations, especially WHO, and clinical trial sites. For further information, please visit www.finddx.org

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