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

First Successful Field Evaluation of Genedrive® HCV Assay in Africa

Performance Study in Johannesburg Demonstrated 100% Sensitivity and Specificity

genedrive plc, (AIM: GDR), the near patient molecular diagnostics company, today announces successful results of the first field study of its Genedrive® Hepatitis C (HCV) ID Kit in Africa.

The study, performed in Johannesburg at Lancet Laboratories, one of the leading private pathology testing laboratories operating throughout Africa, was designed to verify genedrive HCV’s assay performance across the diverse genotypes which are prevalent in Africa compared to Europe.

In a cohort of 130 clinical samples from South Africa, Kenya, Ghana, Nigeria, Uganda, and other Sub-Saharan countries, the Genedrive® HCV ID Kit demonstrated sensitivity and specificity of 100% compared to the Abbott M2000 HCV Real time assay as a reference. The cohort was composed mostly of HCV genotypes 1a, 4, and 1b, with the remaining 16% samples from genotypes 2, 3, and 5. The test also demonstrated efficiency of 95.4% (result achieved first attempt).

“These positive results with the genedrive HCV assay in customer hands on local samples confirms that our good clinical validation performance can be translated into real-world settings where the test will be used,” said David Budd, Chief Executive Officer of genedrive plc. “Our test is the first to market as a decentralised qualitative molecular HCV test for use at the point of need. We remain confident it can play an important role in the diagnosis and management of the disease in Africa and in other territories where access to centralized laboratories is limited.”

Dr Allison Glass, Pathologist-in-Charge at Lancet Laboratories Johannesburg commented, “Our trained laboratory staff found the Genedrive® HCV system and kit easy to operate, and, compared to the Abbott M2000 platform, required no maintenance, had a small laboratory foot print and faster processing time. Many of the original samples were haemolysed but produced valid results first time demonstrating the robustness of using PCR direct from plasma. The genedrive HCV kit has the potential to decentralise clinical management of chronic HCV, which may result in the expansion of treatment programmes to rural areas of resource-limited countries.”

The study follows the recent announcement that genedrive plc has signed a distribution agreement with Sysmex Europe GmbH, a subsidiary of Sysmex Corporation, a world leader in clinical laboratory systemization and solutions, for the Genedrive® HCV ID Kit and Genedrive® platform in the EMEA region with an initial focus on Africa. genedrive plc also entered into a distribution agreement with Sysmex Asia Pacific Pte Ltd, a subsidiary of Sysmex Corporation, for its CE-marked Genedrive® HCV ID Kit and Genedrive® platform in the Asia Pacific region.

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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 Kit has recived CE marking. Further details can be found at: www.genedriveplc.com and www.genedrive.com

About Sysmex Europe
Sysmex Europe GmbH (SEG), located near Hamburg, Germany, is a subsidiary of the Sysmex Corporation from Kobe, Japan. From our Hamburg offices - designated a Great Place to Work® in 2014 and 2016 - we serve our affiliates, distributors and customers throughout EMEA - Europe, the Middle East and Africa. Globally we employ around 8000 staff, of whom 1300 work in the EMEA region. Sysmex is the global leader in haematology and a renowned specialist in haemostasis, urinalysis, and laboratory automation. As our expertise in the interdependency of disease and medical disciplines grows, we are growing to cover other pressing areas such as oncology, flow cytometry, liquid biopsy and essential healthcare in resource-poor regions. This is allowing us to deliver clinical value that primary healthcare workers such as physicians, surgeons and other specialists can use directly to deliver better diagnostics, treatment and monitoring, and so improve the quality of life of their patients. Everything we do is driven by a single mission: Shaping the advancement of healthcare. For more information about Sysmex Europe, please visit www.sysmex-europe.com, and for details on Sysmex Africa www.sysmex.co.za

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.