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REACH

genedrive plc
("genedrive" or the "Company")

Excellent performance of Genedrive® HCV -ID Kit in large multi-centre study

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, announces the publication of a large independent multi-centre study evaluating the real-world performance of the Genedrive® HCV - ID Kit in low and middle income countries. The study yielded sensitivity specifications of 96.2 - 100%, and specificity specifications of 98.7 - 99.5%, depending on the site or viral load. The results confirm that the Genedrive® HCV -ID Kit is effective as intended in the diagnosis of HCV infection in resource limited settings. Importantly, the authors highlight a test fail rate of only 1.6%, showing that the Genedrive® system performs to this high standard even though the system operators in the study had no previous experience in molecular testing.

The study, published in the journal Diagnostics (Lamoury et al, 2021, 11, 746) was conducted in Georgia and Cameroon, and enrolled 426 participants, which had very different demographic backgrounds. The participants in the Georgia trial were almost all intravenous drug users. Intravenous drug users are a key patient population for HCV infection. The Genedrive sensitivity and specificity results were obtained by comparison to testing with the Abbott RealTime HCV Assay. The publication can be accessed on line at https://www.mdpi.com/2075-4418/11/5/746. The study was conducted by The Foundation for Innovative New Diagnostics (FIND), with grant funding provided by Unitaid.

The study's findings also corroborate other key performance capabilities of the Genedrive® HCV -ID Kit, including the ability of the kit to identify all major HCV genotypes, the utility of requiring small volumes of plasma, and the lack of hazardous chemicals in the Genedrive kits construction, allowing for normal disposal processes versus competitor products that require heat incineration.

David Budd, Chief Executive Officer of genedrive plc, said: *"This study is the first large scale, independent multi centre evaluation from low and middle income markets using the Genedrive HCV test. While the performance results are as expected and excellent, it is equally gratifying to see these achieved with operators with no previous experience in molecular testing. Moving testing from highly complex and automated central hospital settings towards more simple decentralised settings is a balance of technological complexity, cost, performance, and usability, which is not always an easy balance to achieve. This study is an excellent demonstration of real world performance and the ability of Genedrive to contribute to fighting HCV in resource limited settings."*

The Genedrive® HCV - ID Kit allows for decentralised molecular testing of Hepatitis C (HCV) by PCR, providing results within 90 minutes direct from a small plasma sample (30 µl). This allows for testing to be done outside of a large hospital facility and indeed while a patient may be waiting for a result. The assay is performed on the Genedrive® platform, the only truly portable molecular diagnostics system designed for diagnosing HCV at the point of need.

For further details please contact:

genedrive plc +44 (0)161 989 0245
David Budd: CEO / Matthew Fowler: CFO

Peel Hunt LLP (Nominated Adviser and Joint Broker) +44 (0)20 7418 8900
James Steel / Victoria Erskine

finnCap (Joint Broker) +44 (0)20 7220 0500
Geoff Nash / Kate Bannatyne / Alice Lane

Walbrook PR Ltd (Media & Investor Relations) +44 (0)20 7933 8780 or genedrive@walbrookpr.com
Paul McManus / Anna Dunphy +44 (0)7980 541 893 / +44 (0)7876 741 001

About genedrive plc (http://www.genedriveplc.com)
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 Company has assays on market for the detection of HCV, certain military biological targets, and has tests in development for tuberculosis (mTB). The Company recently released a high throughput SARS-CoV-2 assay and has in development a Genedrive® Point of Care version of the assay, both based on Genedrive® chemistry.