4 May 2020

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

Genedrive® HCV-ID test receives WHO Prequalification

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, announces it has received World Health Organisation (WHO) Prequalification for the Genedrive® HCV ID kit. This represents the first Genedrive product to have received prequalification status, and the Genedrive HCV ID kit is the first portable point of need HCV device to have received WHO PQ.

Upon prequalification, the Genedrive® HCV ID kit will be included in the WHO list of prequalified in vitro diagnostics (IVDs) and becomes eligible to participate in the procurement processes of UN agencies. WHO Member States are encouraged to use the WHO list of prequalified IVDs for their respective procurement decisions. The prequalification process consists of a transparent, scientifically sound assessment of products, which includes an independent performance evaluation and site visits to the manufacturer to audit the quality system and product dossiers.

David Budd, Chief Executive Officer of genedrive plc, said: “We are delighted to have reached this important milestone in the evolution of our company and in our efforts to tackle the real problem of undiagnosed HCV infection in low and middle income countries. The WHO PQ process itself was very rigorous and we are pleased to have our HCV products validated through their independent audit and laboratory testing processes. WHO PQ will support the commercial processes of our distribution partners in many countries and evidences genedrive’s product development and vigilance processes to this important agency.”

The Genedrive® HCV-ID kit allows for decentralised molecular testing of HCV by PCR, providing results within 90 minutes direct from a small plasma sample (25ul). 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.

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 announced the development of a high throughput SARS-CoV-2 assay, based on Genedrive® PCR chemistry.