16 June 2023

genedrive

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

Multi-partner grant awarded for the validation of Genedrive® CYP2C19 ID Kit in time critical NHS settings

Manchester NHS Industry partnership programme for rapid genomic test implementation

genedrive plc (the "Company"), the point of care molecular diagnostics company, today announces its participation in a multi-partner grant award ("DEVOTE") from Innovate UK and the UK government Innovation Accelerator programme with funding expected to be made available to further the validation and implementation of the new Genedrive® CYP2C19 ID Kit pharmacogenetic test in a time critical clinical setting.

The Development and Validation of Technology for Time Critical Genomic Testing (DEVOTE) grant will provide acute care patient access and supporting infrastructure for the Company to assess the real world clinical performance of time-critical clinical tests in an NHS settings. The programme, led by the University of Manchester (UoM), builds on the model of the previous successful UoM/genedrive partnership with the PALOH programme, which supported the development and evaluation of the Genedrive[®] MT-RNR1 ID Kit which has recently received a recommendation from NICE.

DEVOTE pulls together health economists, clinicians, informaticians, and researchers to quickly access new technologies, and provide feedback in an iterative fashion. Genedrive's CYP2C19 ID Kit is one of three exemplar projects to be included in the programme which is expected to be funded through the Innovate grant, in-kind contributions, and other aligned funding. In the main, funding is expected to go directly to the UoM and its NHS partners to set up and coordinate the three projects, the total amount of funding to be made available under the programme will be determined in due course.

DEVOTE will focus on ischaemic stroke patients in acute care who are targeted to be prescribed Clopidogrel to prevent further clot formation. Clopidogrel is less efficacious in individuals with certain genetic CYP2C19 variants because they do not metabolize Clopidogrel effectively. Genedrive's CYP2C19 ID Kit is being developed to provide guidance at the point of care on which patients will respond fully to Clopidogrel. Patients with gene variants that result in reduced or loss of function of CYP2C19 can be given alternative treatments.

Programme participants include genedrive, the University of Manchester (UoM), Health Innovation Manchester and Manchester University NHS Foundation Trust (MFT). The DEVOTE programme will be led by Professor William Newman, Professor of Translational Genomic Medicine at the University of Manchester and Consultant at Saint Mary's Hospital, part of Manchester University NHS Foundation Trust. Additional and ongoing project information is available at https://www.devoteprogramme.co.uk/

Professor William Newman said: "We look forward to working with genedrive and our other DEVOTE programme colleagues in Manchester to develop a framework for time-critical pharmacogenetics, and to provide the framework for assessment of implementation of the Genedrive® CYP2C19 ID Kit in emergency care. DEVOTE will further establish the Manchester environ as a world recognised centre for the development and implementation of pharmacogenomic testing."

David Budd, Chief Executive Officer of genedrive plc, said: "DEVOTE is an amazing opportunity to engage formally with a health system like the NHS to demonstrate the effectiveness of a new diagnostic approach. Access to the Acute Medicine Unit in real time has considerable value to genedrive as further funding would allow us to progress ongoing product development quickly and efficiently, and would support the pathway to clinical validation of our Genedrive® CYP2C19 ID Kit. This level of clinical input and evaluation is increasingly required by regulatory authorities prior to marketing product especially in the EU. We are privileged to continue with our partners at UOM and MFT in developing time-critical genetic test solutions."

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About genedrive plc (<u>http://www.genedriveplc.com</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 Company has assays on the market for the detection of MT-RNR1, HCV, certain military biological targets, a high throughput SARS-CoV-2 assay and a point of care test for Covid-19. The company are currently developing a genetic test for CYP2C19 metaboliser status.

About DEVOTE

The Development and Validation of Technology for Time Critical Genomic Testing (DEVOTE) Programme is a collaboration between academics, clinicians, and industry partners. It aims to accelerate the adoption of genomic technology into clinical practice by supporting companies through each aspect of the translational pathway.

For more information contact info@devoteprogramme.com.