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

NHS Ethics approval for use of AIHL test in hospital trials

First ever research ethics approval for a neonatal point of care genetic test
Opportunity for widespread NHS adoption of test for prevention of hearing loss in newborns

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, announces that full ethics approval from the NHS Health Research Authority and ethics committee has been received for the use of the Company's Antibiotic Induced Hearing (AIHL) test in hospital trials for clinical validation. The Company believes that this represents the world's first ethical approval for a point of care genetic test used to influence neonatal management in an acute setting.

The novel AIHL test, which genedrive has developed for evaluation by the Manchester Centre of Genomic Medicine, will be used in the PALOH ("Pharmacogenetics to Avoid Loss of Hearing") study involving approximately 1,000 patients from two large UK intensive care units. The trial is planned to commence in November 2019 and run for circa six months.

The Genedrive® MT-RNR1 screening assay targets individuals with the m.1555A>G genotype, which is estimated to occur in 1:500 people. If a baby who has the mutation is given gentamicin, they can go profoundly deaf. In the UK alone, there are approximately 90,000 babies treated for bacterial infections with gentamicin each year that are candidate patients for this screening test.

The test is performed on the Genedrive molecular platform, using a single-use, disposable cartridge, and can deliver a rapid genetic result in under 30 minutes, allowing the opportunity to alter treatment as needed within the one hour treatment window stated in the current NICE treatment guidelines.[1]

The simple test has been developed for use by the nursing staff in a point of care setting. The primary objective of the PALOH study will be to show how well the Genedrive® MT-RNR1 test platform can be implemented into the current neonatal emergency admissions process.

genedrive intends to demonstrate the health economic benefits of the test to the NHS to gain adoption, in addition to European healthcare settings. Successful implementation of

the Genedrive test would be a first in the integration into emergency care settings of a rapid decision making, genetic-based test for safe antibiotic use in the UK NHS.

David Budd, Chief Executive Officer of genedrive plc, said: *"We are very pleased with our involvement in the PALOH study, and the progress we and our colleagues in Manchester and Liverpool have made to date is truly impressive. This type of test fits very well with our strengths - single use, low complexity, cost effectiveness and rapid speed to result. The opportunity to bring the power of molecular testing in a point of care acute setting will undoubtedly significantly improve the lives of patients both in this trial and in future adoption of MT-RNR1 testing."*

Notes

1. National Institute for Health and Care Excellence, Neonatal infection (early onset): antibiotics for prevention and treatment (2012) NICE

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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 test 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 SE Asia (ex-India), and with ARKRAY Healthcare pvt Ltd for the distribution of the Genedrive® HCV ID Kit and Genedrive® platform in India. The company also has test in development for tuberculosis (MTB) and Antibiotic Induced Hearing Loss (AIHL)

Further details can be found at: www.genedriveplc.com and www.genedrive.com

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