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

Antibiotic Induced Hearing Loss Assay receives CE marking

genedrive's genetic screening test could prevent thousands of infants from needlessly going deaf

genedrive plc (LSE: GDR), the near patient molecular diagnostics company, announces that its Antibiotic Induced Hearing Loss test, the Genedrive® MT-RNR1 ID kit, has obtained CE marking. The Genedrive® MT-RNR1 ID kit will be used in critical care settings to screen babies for a genetic mutation, which if present, can cause lifelong deafness when they are given certain antibiotics.

genedrive's RNR1 test is believed to be the first example of a commercial genetic screening test designed for use in an infant emergency care environment. Some infants are born with a mutation in their MT-RNR1 gene, making them susceptible to lifelong, profound hearing loss if given the frontline antibiotic gentamicin. Infants with suspected infection need to be treated with antibiotics within one hour (National Institute for Health and Care Excellence) of arriving in a neonatal intensive care unit. The current genetic tests that check the risk of hearing loss associated with gentamicin treatment are done from a hospital's centralised Genetics Department, and typically take 3-5 days to return results. This does not meet the one hour requirement of an urgent care setting. The Genedrive test allows patients to be screened for the mutation upon admission in less than 30 minutes, and those that are found to have the gene mutation can be prescribed an alternative, safer treatment.

David Budd, Chief Executive Officer of genedrive plc, said: *"We are very pleased to have achieved this important milestone, pioneering the availability of the first genetic acute care test for infants. CE marking of our RNR1 test allows for the next phase, with implementation evaluation by our NHS partners in Manchester and Liverpool. At the same time, we will look to the opportunities outside of the UK where CE marking gives us market entry."*

Professor William Newman, Clinical Head of Division in Genomic Medicine Manchester University NHS Foundation Trust, commented: "*We have been very pleased to partner with genedrive in the development and availability on the antibiotic induced hearing loss test. We are planning to deploy use of the test across Manchester and Liverpool for the next 6-8 months, to show how it can be successfully implemented in an NHS environment. There is a huge level of enthusiasm on the sites*

amongst our neonatal consultants, nursing staff, and patient groups as we launch a truly novel genetic test that offers the possibility of improving the lives of thousands of babies and their families."

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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® mt-RNR1-ID kit has received CE-IVD Certification and will be launched into Europe and other markets following full evaluation by the UK National Health Service. The Company has assays on market for the detection of HCV, certain military biological targets, and has tests in development for tuberculosis (mTB).

About Antibiotic Induced Hearing Loss

Aminoglycosides are broad-spectrum antibiotics, and are one of the most frequently prescribed medicines globally, used in cases of gram-negative sepsis, pseudomonas colonisation and treatment of multi-drug resistant tuberculosis.

The National Institute for Health and Care Excellence (NICE) advises the use intravenous benzylpenicillin with gentamicin as the first-choice antibiotic regimen for empirical treatment of suspected infection in the neonatal period (NICE CG149). This combination has the major advantage of having a narrow spectrum of activity and lower risk of antibiotic resistance compared to alternative antibiotic regimens.

The side effect profile from protracted courses of aminoglycosides is well known, with ototoxicity commonly recognised in some patients. Antibiotic Induced Hearing Loss

clusters within families, and is caused by a mutation in the 12S rRNA (RNR1) m.1555A>G. The incidence is estimated at about 1 in 500. In the UK, 90000 babies are admitted to NICU units each year, and 80-85% of them receive gentamycin.

It has previously been observed that genetic testing should be used in children requiring aminoglycosides to prevent hearing loss and that this approach would be cost-effective when balanced against the costs of lifelong deafness and the cost of bilateral Cochlear implants. However, prior to the Genedrive test, no system has existed that could meet this need in a critical care environment.

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

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