

3 March 2021

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

**Antibiotic Induced Hearing Loss update**  
***New clinical guidance in the UK supports assay***

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, provides an update on its Antibiotic Induced Hearing Loss (“AIHL”) assay.

As announced on the 3 December 2020, an 11 month implementation trial at Manchester University NHS Foundation Trust and Liverpool Women’s Hospital successfully concluded in November 2020. The results of the study will be published in a peer reviewed journal. The study’s primary outcomes were very positive, showing genedrive’s utility as the world’s first rapid genetic test in an emergency care neonatal setting. In excess of 750 babies were tested and 160 hospital staff were trained to provide rapid testing in this critical care setting.

Since completion of the trial, there has been new clinical guidance in the UK<sup>1</sup> on the importance of the management of specific genetic mutations and their role in hearing loss as a result of antibiotics (“ototoxicity”). Government and Society guidance are considered a key factor influencing the speed and extent of future adoption. The Company and Inspiration Healthcare Group plc (AIM: IHC), the distribution partner for the AIHL assay, believe this will lead to increased demand for the genedrive AIHL test in the UK. This new government guidance reminds healthcare professionals about the impact of antibiotic related ototoxicity and to consider the need for genetic testing prior to initiation of treatment. genedrive’s assay is the only commercial point of care test available for the testing of MT-RNR1, the most important mutation contributing to AIHL in infants.

The launch of the genedrive AIHL assay remains on track for summer 2021 and the Company is enthusiastic about both the commercial prospects and the clinical benefits of this novel test to prevent potential irreversible hearing loss and this test becoming a standard of care. The Company is executing initial stage key opinion leader engagement in the UK alongside Inspiration Healthcare in preparation for commercial launch.

**David Budd, CEO of genedrive plc, said:** *“We had the privilege of working with Manchester University NHS Foundation Trust and Liverpool Women’s Hospital throughout 2020 on the first deployment globally of a point of care test system to screen for MT-RNR1 – a mitochondrial mutation closely associated with ototoxicity in infants. Despite the emergence of COVID-19, our clinical partners showed huge dedication in keeping this important project on-track, becoming the first in the world to generate valuable information on the utility of this approach in an emergency care setting. As we see updated guidance and greater awareness to the requirement for genetic testing, we only expect increased interest in our novel assay.”*

<sup>1</sup><https://www.gov.uk/drug-safety-update/aminoglycosides-gentamicin-amikacin-tobramycin-and-neomycin-increased-risk-of-deafness-in-patients-with-mitochondrial-mutations>

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**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.