

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

New Genedrive® system readied for Antibiotic Induced Hearing Loss launch

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, provides an update on a new Genedrive® system platform which has been designed for the upcoming launch of the Genedrive® MT-RNR1 assay, used for the detection of Antibiotic Induced Hearing Loss ("AIHL") in newborns.

The Genedrive® MT-RNR1 assay targets the m.1555A>G mutation genotype. If a baby carrying the mutation is given the antibiotic gentamicin, a common treatment for bacterial infections, it can cause lifelong deafness. In the UK, there are approximately 90,000 babies admitted to NICUs each year who could benefit from this screening test.

A large-scale implementation trial of the Genedrive® MT-RNR1 assay was performed on 750 newborns by Manchester and Liverpool Hospitals and concluded in November 2020. The trial represented the world's first use of a genetic point of care test in a Neonatal Intensive Care (NICU) setting. The results of this innovative trial have now been submitted by the study team for publication. Extensive feedback was taken from over 150 nurses who performed AIHL testing over the trial period and this has resulted in a number of refinements being made to the Genedrive® unit design principally to further enhance usability in a NICU setting.

Improvements have been made to the cartridge and instrument interface and data management options, as well as onward results transmission capability. The new Genedrive® system has a 7-inch integrated touch screen, replacing the separate smartphone configuration that was used in the trial. This avoids the issue of a misplaced phone or the complication of users trying to run multiple Genedrive® units from a single smartphone. The Graphical User Interface ("GUI") menus have been streamlined and larger data fields capture NICU specific clinical and patient parameters. This reduces interaction time and decreases any chances for delays due to missing field information. The size of the Genedrive® system has been increased to support the new GUI screen. The patented Genedrive® assay cartridge has also been modified with a clip mechanism to ensure an auditory 'click' when the cartridge is fully inserted and engaged in the instrument. The cartridge is also now enabled with an RFID¹ electronic lock to prevent the use of expired reagents.

The Company will be seeking CE mark clearance for the new Genedrive® system in the coming weeks prior to commercial launch:

<https://www.genedrive.com/genedrive-system/genedrive-system.php>

David Budd, CEO of genedrive plc, said: *"It has been very rewarding to see the positive effect of point of care AIHL testing, and the feedback and engagement of the NHS teams has been a tangible benefit to the Company and will ultimately be a key driver of adoption in the market place. Following this refinement of the overall AIHL system, we are looking forward to the impending commercial launch and the improved healthcare outcomes it will offer as an innovative point of care test in a NICU care setting. Many children every year will be able to live profoundly different lives as a result of this successful development collaboration."*

1. Radio Frequency Identification

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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 and certain military biological targets. The Company recently released a high throughput SARS-CoV-2 assay and has a point of care version of the SARS-Cov-2 test due on market during 2021.

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