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

PALOH study results published in JAMA Pediatrics

Publication confirms Genedrive® MT-RNR1 test's role in avoiding antibiotic related hearing loss in infants

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, announces that the Pharmacogenetics to Avoid Loss of Hearing ("PALOH") trial, conducted at Manchester and Liverpool Hospitals to assess the implementation of the Genedrive® MT-RNR1 ID kit, has now been published in the Journal of the American Medical Association for Pediatrics ("JAMA Pediatrics"), which is the top ranked medical journal in pediatric medicine.

The accompanying editorial describes the application of the Genedrive® MT-RNR1 ID kit testing approach as "entering a new era", and "an important step" in the management of neonatal sepsis. The editorial also observes that identification of the m.1555A>G genetic variant can be performed in the acute setting without disrupting standards of care and that based on a population frequency of the variant and the use of antibiotics in more than seven million neonates each year globally, adoption of a MT-RNR1 point of care test would potentially avoid antibiotic induced hearing loss in thousands annually.

The PALOH study represented the world's first trial of a genetic Point of Care Test (POCT) designed to alter patient management in an acute, time-sensitive setting. The Genedrive® MT-RNR1 assay was used to screen for a genetic variant called m.1555A>G. If a baby carrying the gene variant is given the antibiotic gentamicin, a common treatment for bacterial infections, it can cause lifelong deafness.
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A total of 751 neonates were recruited to the PALOH study throughout 2020. Three babies with the m.1555A>G variant were identified, all of whom avoided aminoglycoside antibiotics and therefore avoided profound hearing loss. The assay had a real-world analytical sensitivity of 100%, a specificity of 99.2% and an accuracy of 99.2%. The mean time to antibiotics was equivalent to previous practice, indicating that the test can be introduced into routine practice.

The study design of this trial allowed improvements to the system based on study data and clinical feedback, leading to a greatly improved system for commercialisation and clinical implementation. Throughout the trial, the MT-RNR1 hardware platform (Genedrive®) was updated to improve user efficiency (proportion of tests returning valid results) and accuracy. Repeated testing of samples where testing had previously failed demonstrated an improved performance rate of 94.3% when performed in the intended-use clinical setting and 100% when performed in a laboratory setting.

David Budd, CEO of genedrive plc, said: *"The PALOH study demonstrates the ease of use and capability of the Genedrive® technology to deliver rapid genetic information in a very time sensitive acute care situation, a diagnostic advancement that has not been demonstrated previously with other commercial platforms. The conclusions in JAMA Pediatrics validate our intent in this market – there are millions of neonates exposed to antibiotics annually and our test could potentially prevent thousands going deaf each year. The PALOH study is a seminal document to support our commercial efforts going forwards."*

The JAMA Pediatrics paper, entitled "Rapid Point-of-Care Genotyping to Avoid Aminoglycoside-Induced Ototoxicity in Neonatal Intensive Care" was authored by Dr. John McDermott et al, and is printed in the 21st March 2022 edition of the Journal. The paper can be viewed here: https://tinyurl.com/kvusm8ts

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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 a high throughput SARS-CoV-2 assay. The Company recently released point of care test for Covid-19.