9 February 2023

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

**THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION AS DEFINED IN ARTICLE 7 OF REGULATION (EU) NO 596/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 16 APRIL 2014 ON MARKET ABUSE (MARKET ABUSE REGULATION) AS RETAINED AS PART OF UK LAW BY VIRTUE OF THE EUROPEAN UNION (WITHDRAWAL) ACT 2018 AS AMENDED**

**Antibiotic Induced Hearing Loss test receives preliminary recommendation by NICE**
*NICE enters public consultation phase of Early Value Assessment of the Genedrive® MT-RNR1 System*

genedrive plc (AIM:GDR), the point of care molecular diagnostics company, announces that the UK's National Institute for Health and Care Excellence (NICE) has preliminarily recommended that the Genedrive® MT-RNR1 ID Kit can be used by the NHS following the evidence review as part of their Early Value Assessment (EVA) Programme[1].

The specialist NICE EVA committee collected evidence regarding technical, clinical, economic and social impact of the Genedrive® MT-RNR1 ID Kit and concluded that:

- the Genedrive® MT-RNR1 ID Kit can quickly and accurately identify babies with the primary genetic variant who may be at risk of hearing loss if given aminoglycoside antibiotics.
- there is currently no test available in the NHS that provides results quickly enough to inform decisions on antibiotic prescribing in emergency care.
- the long-term savings to the NHS associated with hearing loss and fitting cochlear implants could be substantial.
- aminoglycoside-induced hearing loss has a major negative impact on the quality of life of children and their families.

NICE's final guidance on the Genedrive® MT-RNR1 ID Kit will follow a public consultation period which opens today, 9 February and closes on 21 February 2023. The final recommendations will be the basis for NICE's early value guidance on using the Genedrive® MT-RNR1 test in NHS England alongside additional data generation.

Further information can be found at (please note this link will go live later today): Consultation | Early Value Assessment: Genedrive MT-RNR1 ID Kit for detecting single nucleotide polymorphism m.1555A>G in neonates | Guidance | NICE

**David Budd, CEO of genedrive plc, said**: "*We are delighted with the enthusiastic and positive engagement of the NICE specialist review team and encouraged by this draft stage recommendation from the EVA programme. We encourage relevant stakeholders to participate during the public consultation period to support our pioneering work, and look forward to receiving the final NICE report and recommendations for the world's first rapid point-of-care genetic test used to influence neonatal management in an acute care setting. The timely publication of the NICE guidance is an important outcome that we expect will facilitate further uptake and adoption of the test by NHS England.*"

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## 1. Further Information on the EVA Programme

NICE's new EVA programme engages clinicians and developers around innovative technologies that because of recent introduction, still have their real-world evidence base developing. The new EVA process allows for a recommendation for use in the NHS while real world data collection continues. The new EVA programme means that patients can benefit from promising new products sooner. The outcomes of a NICE review can be (i) to conditionally recommend use while further data is collected, (ii) that a product should be used for research only, or (iii) a product is not recommended.

**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 the market for the detection of MT-RNR1, HCV, certain military biological targets, a high throughput SARS-CoV-2 assay and a point of care test for Covid-19. The company are currently developing a genetic test for CYP2C19 metaboliser status.

The Genedrive® MT-RNR1 ID Kit, selected as 1 of the 10 EVA pilot projects, is the world's first commercial point-of-care genetic test for emergency care. It helps to avoid irreversible lifelong hearing loss in specific infants exposed to aminoglycosides by rapidly detecting the m.1555A>G gene variant that can cause lifelong deafness, allowing for alternative antibiotics to be prescribed. Product information can be found at https://www.genedrive.com/assays/rnr1-product.php