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

Genedrive® MT-RNR1 ID Test receives positive final recommendation by NICE
NICE issues final guidance for use in the NHS through Early Value Assessment programme

genedrive plc (AIM:GDR), the point of care molecular diagnostics company, announces that, further to the Company's announcement on 9 February 2023, the UK's National Institute for Health and Care Excellence (NICE) has today ratified and finalised its recommendation following a public consultation process that the Genedrive® MT-RNR1 ID Kit can be used by the NHS. The review was conducted through NICE's Early Value Assessment (EVA) programme, which was designed to select and recommend new technologies that will make a real difference to patients and provide the most value for the NHS.

The positive outcome was based on a number of key conclusions, including that the Genedrive® MT-RNR1 ID Kit can quickly and accurately identify babies with the MT-RNR1 genetic variant who may be at risk of hearing loss if given aminoglycoside antibiotics, and that no other test is available to provide results quickly enough to inform decisions on antibiotic prescribing in emergency care. These conclusions support, and are a consequence of, the Company's strategy for the development of rapid molecular diagnostics for emergency care.

David Budd, CEO of genedrive plc, said: "*We are appreciative of the thorough review conducted by the NICE team. The final report issued today entirely reflects the preliminary conclusion published in February. As we continue with commercial roll out and product adoption, the NICE EVA framework will give us the opportunity to support specific performance and impact data that NHS users and commissioners may look for in future guidance. NICE, whose guidance is formally applicable to the NHS in England and Wales, is an internationally respected health authority and the tools and data supplied in its review will be relevant to the rest of the United Kingdom and to the other international markets which we are now accessing.*"

NICE's recommendation on using the Genedrive® MT-RNR1 test in NHS England and Wales through its EVA program will support additional data generation requirements whilst the test is being used routinely within NHS sites. It is anticipated that this data collection process will be several years in duration. Further guidance on data collection from NICE is expected in the coming months.

NICE's final EVA report can be accessed here: https://www.nice.org.uk/guidance/indevelopment/gid-hte10009/documents

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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 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