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

New Genedrive® System receives CE-IVD marking
Device ready for Antibiotic Induced Hearing Loss launch

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, announces that the new generation Genedrive® System platform, which has been developed to support the commercial launch of the Genedrive® MT-RNR1 ID Kit, has now received CE-IVD marking in anticipation of launch into the UK and EU. The Genedrive® MT-RNR1 assay is used to screen for a genetic mutation called m.1555A>G. If a baby carrying the mutation is given the antibiotic gentamicin, a common treatment for bacterial infections, it can cause lifelong deafness. The Genedrive® test allows for the administration of alternative treatments if the mutation is detected, avoiding the life changing impacts and costs of antibiotic induced hearing loss ("AIHL").

Following user feedback from the successful PALOH* study, various product improvements and refinements have been incorporated into this next generation platform. These include informatic and ergonomic improvements. The new system has been validated by external users as part of the CE-IVD marking process and is ready to be deployed initially at key sites in the UK, followed by the EU. A system overview is available at www.genedrive.com/genedrive-system/genedrive-system.php

genedrive is now commencing its roll out of the Genedrive MT-RNR1 IC Kit in partnership with Inspiration Healthcare plc as its distributor in the UK and Ireland, and is expecting its first sales in autumn 2021. The Company estimates the total addressable market in the UK and EU at around £35m and has recently raised funds to support its commercial activities to drive sales and exploit thus attractive market.

Professor Bill Newman, said:** "*The use of the Genedrive® MT-RNR1 system in our neonatal intensive care units represented the first time point of care molecular diagnostics has been ever used in this urgent care situation. Antibiotics should be delivered within an hour of any decision to treat, and current lab-based genetic technologies are not sufficiently rapid to detect the MT-RNR1 mutation within a clinically relevant timeframe. Our engagement with genedrive in the PALOH study has been very positive as well and rewarding for our teams. It's very encouraging to see the Company quickly incorporate the study findings and our teams' suggestions into this next generation platform, which we think will support the urgent need of ensuring antibiotic induced hearing loss can be significantly reduced."*

David Budd, CEO of genedrive plc, said: *"Developed in partnership with NHS collaborators, the Genedrive® MT-RNR1 Kit and Genedrive® System represent several world firsts – the first commercial availability of an MT-RNR1 test, the first use of our new Genedrive® platform, and the first use of point of care molecular diagnostics in a neonatal urgent care setting. The excellent clinical and performance data that supports these new innovations puts us in a strong position for commercial roll out in the UK alongside Inspiration Healthcare, our commercial distributors in the UK and Ireland.*

"With the EU scheduled to follow early next year, our first EU pilot site is already established, and will serve as a reference site as we target selected EU countries. The creation, development, and evaluation of the AIHL test and the new Genedrive® System to support the kit has been very considered, and we are pleased to be at the forefront of this innovation in patient care."

*The prospective Pharmacogenetics to Avoid Loss of Hearing (PALOH) Trial was a prospective performance trial led by Manchester University NHS Foundation Trust and NIHR Manchester Biomedical Research Centre. It was designed assessed the proportion of neonates that could successfully tested for the mt-RNR1 variant on admission vs the number of neonates prescribed antibiotics. Secondary outcomes measured whether implementation maintained existing routine clinical admission practices. The study authors have submitted the results for publication, a summary of which was recently been presented at the European Society for Human Genetics.

** Dr Newman is Professor of Translational Genomic Medicine at the University of Manchester, Consultant at Saint Mary's Hospital, part of Manchester University NHS Foundation Trust and National Institute for Health Research (NIHR) Manchester Biomedical Research Centre, Developing Genetic and Genomic Solutions, Associate Lead.

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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.

About The University of Manchester
The University of Manchester, a member of the prestigious Russell Group, is one of the UK's largest single-site university with more than 40,000 students – including more than 10,000 from overseas. It is consistently ranked among the world's elite for graduate employability. The University is also one of the country's major research institutions, rated fifth in the UK in terms of 'research power' (REF 2014). World-class research is carried out across a diverse range of fields including cancer, advanced materials, global inequalities, energy and industrial biotechnology.

About Manchester University NHS Foundation Trust MFT
Manchester University NHS Foundation Trust (MFT) is one of the largest NHS Trusts in the country and a leading provider of specialist healthcare services. Its nine hospitals are home to hundreds of world class clinicians and academic staff committed to finding patients the best care and treatments.

Its hospitals are Manchester Royal Infirmary, Saint Mary's Hospital, Royal Manchester Children's Hospital, Manchester Royal Eye Hospital, University Dental Hospital of Manchester, North Manchester General Hospital, Trafford General, Altrincham Hospital, Wythenshawe Hospital and Withington Hospital. More information is available at www.mft.nhs.uk.

About the NIHR Manchester Biomedical Research Centre
The NIHR Manchester Biomedical Research Centre (BRC) is hosted by Manchester University NHS Foundation Trust and The University of Manchester, in partnership with Salford Royal NHS Foundation Trust and The Christie Hospital NHS Foundation Trust.
The BRC's vision is to drive health improvements and lasting change for all through creative, inclusive and proactive research that identifies and bridges gaps between new discoveries and individualised care.
Funded by the NIHR from 2017-2022, Manchester BRC provides world-leading research into:

- Biomarker Platforms
- Cancer
- Dermatology

- Informatics and Data Sciences
- Hearing Health
- Musculoskeletal Disease
- Respiratory Disease

About the National Institute for Health Research (NIHR)
The mission of the National Institute for Health Research (NIHR) is to improve the health and wealth of the nation through research. We do this by:

- funding high quality, timely research that benefits the NHS, public health and social care
- investing in world-class expertise, facilities and a skilled delivery workforce to translate discoveries into improved treatments and services
- partnering with patients, service users, carers and communities, improving the relevance, quality and impact of our research
- attracting, training and supporting the best researchers to tackle complex health and social care challenges
- collaborating with other public funders, charities and industry to help shape a cohesive and globally competitive research system
- funding applied global health research and training to meet the needs of the poorest people in low and middle income countries.

NIHR is funded by the Department of Health and Social Care. Its work in low and middle income countries is principally funded through UK Aid from the UK government.