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Genedrive PLC
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genedrive plc

("genedrive" or the "Company")

Completion of PALOH-UK Patient Recruitment for Genedrive® MT-RNR1 ID Kit

- *Nearly 6,000 babies tested across 14 Neonatal Intensive Care Units*
- *Clinical cohort analysis is underway with publication expected around October 2026*

genedrive plc (AIM: GDR), the point of care pharmacogenetic testing company, is pleased to report that Neonatal Intensive Care Unit ("NICU") patient recruitment in the PALOH-UK programme has been completed, with nearly 6,000 babies in neonatal care receiving the Genedrive® MT-RNR1 ID test. Clinical cohort analysis is underway with publication expected in scientific literature around October 2026.

The PALOH-UK programme is funded by the National Institute for Health and Care Research ("NIHR") in collaboration with the UK Government Office for Life Sciences ("OLS") to address the evidence generation requirements of the National Institute for Health and Care Excellence ("NICE") Early Value Assessment ("EVA") of the Genedrive® MT-RNR1 ID Kit.

The programme is led by Professor Bill Newman and Dr. John McDermott, clinical geneticists at the Manchester University NHS Foundation Trust ("MFT") St. Mary's Hospital and was implemented across NICUs of 14 hospitals in the UK to generate further real-world evidence for subsequent assessment and potential revision of guidance to full recommendation.

The Genedrive® MT-RNR1 ID Kit has now exited the NICE EVA pathway and has been selected for technology appraisal under NICE following ministerial referral from the Department of Health and Social Care ("DHSC"). NHS England has communicated an anticipated tender notice publication date of 1 January 2027 and go-live target date of July 2027, subject to NICE guidance outcome. The test currently has conditional recommendation for use in the NHS by NICE and genedrive will continue business case progression as planned to enable PALOH-UK sites to rapidly transition to Business as Usual ("BAU") use. Manchester University NHS Foundation Trust and University Hospitals Sussex NHS Foundation Trust have already successfully transitioned to BAU use.

Dr Gino Miele, CEO of genedrive plc, said: *"We are delighted with successful completion of patient recruitment in the PALOH-UK programme, with nearly 6,000 babies tested across neonatal units in all four UK nations. This represents an important milestone in generating the additional real-world evidence requirements by NICE.*

"To date, more than 13,000 babies have been tested using the Genedrive® MT-RNR1 ID Kit in the UK and internationally, with over 40 babies avoiding aminoglycoside exposure and the risk of lifelong deafness. The PALOH-UK programme is an exemplar of how NHS, academia and industry collaboration, when supported by

government, can successfully translate scientific innovation into measurable patient benefit and deliver life changing patient solutions whilst offering substantial financial and productivity gains to pressured healthcare systems. It also demonstrates in practice the shift from treatment to prevention at the heart of the NHS 10 Year Plan in action."

Dr John McDermott, NIHR Academic Clinical Lecturer, University of Manchester and Co-Chief Investigator of the PALOH-UK programme, said: *"We are delighted to have recruited nearly 6,000 babies to PALOH-UK across 14 neonatal units throughout the UK. This successful recruitment is a real testament to the commitment of the neonatal teams at each participating site, who have integrated the genedrive technology into their routine clinical practice. PALOH-UK demonstrates how genomics can be embedded at the point of care to inform treatment decisions and prevent avoidable harm, aligning closely with the NHS's increasing focus on prevention and personalised care. Analysis of the PALOH-UK dataset is now underway, and we look forward to presenting the findings this autumn to help inform the ongoing NICE assessment."*

Further background

The Company is believed to be the first in the UK to exit the NICE EVA process and subsequently enter the NICE Technology Appraisal process. The regulations require clinical commissioning groups, NHS England and NHS Improvement, and, with respect to their public health functions, local authorities, to comply with NICE technology appraisal guidance that recommends the relevant health service body provide funding within the period specified. When NICE recommends that a treatment be funded by the NHS, the regulations require that the period within which the health service must comply will be stated in the recommendations as 3 months, except when particular barriers to implementation within that period are identified. See here for further details.

If the prevalence observed to date continues to be reflected across the wider NHS population, the number of babies identified each year as being at risk of irreversible aminoglycoside-induced hearing loss ("AIHL") could increase from the c. 200 per year assumed in the original NICE economic model to c. 300 per year. On the same basis, the associated annual NHS cost savings from the avoided cochlear implant procedures alone could increase from c. £13 million to c. £20 million.

Beyond the direct healthcare benefits, the Genedrive® test has the potential to help deliver significant wider societal and economic benefits. NHS Scotland has estimated that broader social care savings associated with avoiding profound aminoglycoside-induced hearing loss could amount to approximately £14.5 million, comprising reductions in the need for additional educational support and lifetime disability-related payments. See here for further details.

When considered alongside the potential reduction in NHS costs associated with cochlear implants and lifelong clinical management, the total economic benefit of routine MT-RNR1 testing may extend substantially beyond the already significant direct healthcare savings.

The Genedrive® MT-RNR1 ID Kit was developed through collaboration involving national funding and policy partners, including the Royal National Institute for Deaf People, NIHR, the Office for Life Sciences, and Innovate UK, alongside Greater Manchester's innovation ecosystem, including; the University of Manchester, Manchester University NHS Foundation Trust, Northern Care Alliance NHS Foundation Trust, Health Innovation Manchester, NIHR Manchester Biomedical Research Centre, the North West Genomic Alliance, Greater Manchester Combined Authority and the Greater Manchester Innovation Accelerator. Together these organisations have supported research, clinical validation, real-world evidence generation, routine NHS implementation and international commercialisation, providing a model for delivering future healthcare innovation across England.

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About genedrive plc (http://www.genedrive.com**).**

genedrive plc is a UK-based, commercial-stage pharmacogenetic testing company focused on rapid, point-of-care diagnostic tests to guide safe and effective drug prescription in emergency and acute care settings.

genedrive's proprietary technology platform enables clinicians to prescribe safer and more effective therapies based on a patient's genetic profile, supporting improved outcomes while reducing pressure on healthcare systems, lowering downstream healthcare costs through the prevention of avoidable complications and earlier, more effective intervention

The Company has two CE-IVD approved and NICE-recommended tests in NHS clinical use. The Genedrive® CYP2C19 ID Kit identifies stroke patients who will not respond to the current standard of care, Clopidogrel, used to reduce risk of secondary stroke. The Genedrive® MT-RNR1 ID Kit helps prevent antibiotic-induced hearing loss (AIHL) in newborns, enabling treatment decisions within actionable timeframes at the point of care.

Headquartered in Manchester, genedrive is focused on scaling UK-developed precision diagnostics within routine care and leveraging real-world evidence to support broader international adoption and commercial growth.

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