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

Scottish Government announcement of investment to support national pharmacogenetic testing of CYP2C19 in Stroke patients and MT-RNR1 in newborn babies in NHS Scotland.

genedrive plc (AIM: GDR), the point-of-care pharmacogenetic testing company, is pleased to note an announcement by the Scottish Government of investment into phased delivery of two national scale pharmacogenetic testing programs utilising genedrive's MT-RNR1-ID and CYP2C19-ID kits in NHS Scotland. The public announcement is available athttps://www.gov.scot/news/improving-health-through-innovation/.

The initial deployment of these programmes is through funding being provided to the Accelerated National Adoption ("ANIA") pathway following referral from ANIA to the Scottish Health Technologies Group ("SHTG") which carried out two technology assessments that included both the Genedrive® CYP2C19 ID Kit and the Genedrive® MT-RNR1 ID Kit. Subsequently, Scotland's First Minister John Swinney delivered a speech on NHS Renewal & Recovery on 27 January 2025 (https://www.youtube.com/live/-tWX1ESlpSs) during which he stated (38:40), "*The latest innovations in genetic testing will be harnessed to enable better targeting of medications, in cases ranging from recent stroke patients to newborn infants with bacterial infections. Smarter care, better care*".

As outlined in the Scottish Government announcement, approximately £800,000 will fund testing newborn babies with genedrive's MT-RNR-ID kit, in a phased national roll out over 18 months with first clinical testing beginning in October. Once fully implemented it is expected that over 3,000 babies per year will receive the MT-RNR1-ID test throughout Scotland. A total of £1.1 million will support interventional CYP2C19 testing in recent stroke patients and whilst primarily focused on laboratory based testing with substantially slower turnaround times, Genedrive's CYP2C19-ID kit will be included for assessment against laboratory testing pathways in Transient Ischaemic Attack ("TIA") clinics.

Dr Gino Miele, CEO of genedrive plc, said:*"This announcement from the Scottish Government is a welcome commitment to the strategic implementation of pharmacogenetic testing into clinical pathways at national scale in NHS Scotland. Aside from enabling significantly better patient outcomes, these interventional testing paradigms offer substantial financial value to pressured healthcare systems. Against a backdrop of increasing paradigm shifts from treatment to prevention and speedier, less centralised diagnostics, and also recent UK government announcements to abolish NHS England as an organisation and loss of 9,000 jobs with accompanying savings of £500m per year, it is noteworthy that CYP2C19 interventional testing<u>alone</u>is estimated to offer one-third of this at approximately £160m per year of value to NHS England. We look forward to working with colleagues*

in ANIA, and are grateful for their integrated efforts and forward strategic thinking in progressing these programs at national level, and we welcome other UK nations adopting a similar integrated national approach to such avoid introduction of regional healthcare inequalities. Genedrive are proud to be at the forefront of enabling the impact of near-patient pharmacogenetic testing and we look forward to updating the market in due course as the contractual and operational planning phases of these programmes are confirmed".

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

genedrive plc is a pharmacogenetic testing company developing and commercialising a low cost, rapid, versatile and simple to use point of need pharmacogenetic platform for the diagnosis of genetic variants. This helps clinicians to quickly access key genetic information that will aid them make the right choices over the right medicine or dosage to use for an effective treatment, particularly important in time-critical emergency care healthcare paradigms. Based in the UK, the Company is at the forefront of Point of Care pharmacogenetic testing in emergency healthcare. Pharmacogenetics informs on how your individual genetics impact a medicines ability to work for you. Therefore, by using pharmacogenetics, medicine choices can be personalised, made safer and more effective.

The Company has launched its two flagship products, the Genedrive® MT-RNR1 ID Kit and the Genedrive® CYP2C19 ID Kit, both developed and validated in collaboration with NHS partners and deployed on its point of care thermocycler platform. Both tests are single-use disposable cartridges which are ambient temperature stable, circumventing the requirement for cold chain logistics. The Directors believe the Genedrive® MT-RNR1 ID Kit is a worlds-first and allows clinicians to make a decision on antibiotic use in neonatal intensive care units within 26 minutes, ensuring vital care is delivered, avoiding adverse effects potentially otherwise encountered and with no negative impact on the patient care pathway. Its CYP2C19 ID Kit which has no comparably positioned competitor currently allows clinicians to make a decision on the use of Clopidogrel in stroke patients in 70 minutes, ensuring that patients who are unlikely to benefit from or suffer adverse effects from Clopidogrel receive an alternative antiplatelet therapeutic in a timely manner, ultimately improving outcomes. Both tests have undergone review by the National Institute for Health and Care Clinical Excellence ("NICE") and have been recommended for use in the UK NHS.
The Company has a clear commercial strategy focused on accelerating growth through maximising in-market sales, geographic and portfolio expansion and strategic M&A, and operates out of its facilities in Manchester.

AboutClopidogrel

Clopidogrel is an antiplatelet drug used after IS or TIA to reduce the risk of blood clots that can cause further strokes. Clopidogrel is metabolised into its active form by an enzyme encoded by the CYP2C19 gene which in some people has variations that reduce the enzyme's function which means that clopidogrel does not work as well in these people.The Genedrive® CYP2C19-ID point of care genetic test uses a single, non-invasive cheek swab sample, and rapidly identifies six important genetic variants of the CYP2C19 gene, five of which are instrumental in loss of metabolism function. The Genedrive® System automatically interprets the information for the clinician, allowing prompt administration of an optimised treatment plan, and whilst positioned for near-patient testing is equally amenable to use in laboratory settings.

About Genedrive® MT-RNR1 Kit

The Genedrive® MT-RNR1 kit is the world's first rapid point-of-care test to screen infants in an urgent care setting for a genetic variant that can cause life-long hearing loss when carriers of the variant are given certain antibiotics. Those infants identified by the Genedrive® MT-RNR1 ID kit as carrying the variant can then be given alternative antibiotics. It has the potential to save thousands of children from lifelong hearing loss, whilst providing a net positive financial outcome case to healthcare systems.

About SHTG & ANIA

The Scottish Health Technology Group (SHTG) is a national health technology assessment agency that provides advice to NHS Scotland on the use of new and existing health technologies (excluding medicines), likely to have significant implications for people's care. NHS Scotland is required to consider the advice of the SHTG.

TheAccelerated National Innovation Adoption (ANIA)brings together partners from across NHS Scotland and Scottish Government with complementary capabilities to identify, triage, develop and deliver high impact innovations for deployment at scale, for the benefit of patients across NHS Scotland.

The Genedrive® CYP2C19 ID Kit was included in the Technology Assessment "*Genotype testing to guide clopidogrel use after an ischaemic stroke or transient ischaemic attack ("TIA")*" was used to form an ANIA value case inform decision making on the roll out of CYP2C19 genotype testing in NHS Scotland. The report is available athttps://shtg.scot/our-advice/clopidogrel-genotype-testing-after-ischaemic-stroke-or-transient-ischaemic-attack-tia/

The Technology Assessment "*Genotype testing to guide antibiotic use and prevent hearing loss in neonates*" for the Genedrive® MT-RNR1 ID Kit concluded that genetic testing will be considered for national rollout to hospital wards that care for newborn babies. https://shtg.scot/our-advice/genotype-testing-to-guide-antibiotic-use-and-prevent-hearing-loss-in-babies/

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