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

Scottish Health Technology Group publishes two Technology Assessments including genedrive's CYP2C19 ID and MT-RNR1 and kits

genedrive plc (AIM: GDR), the point-of-care pharmacogenetic testing company, announces that in response to a referral from the Accelerated National Innovation Adoption ("ANIA") collaborative the Scottish Health Technologies Group ("SHTG") has carried out two technology assessments which included both the Genedrive® CYP2C19 ID Kit and the Genedrive® MT-RNR1 ID Kit.

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

Key conclusions of the SHTG assessment relevant to the Genedrive® CYP2C19 ID kit were as follows:

- Using the Genedrive® CYP2C19 ID Kit to identify clopidogrel resistance was resource saving from year two onwards and would also prevent 961 recurrent strokes over a 5-year period and save NHS Scotland approximately £18 million;
- The benefits of antiplatelet therapy are maximised when the patient is started on treatment within 24 hours of the initial stroke or TIA. Laboratory-based testing, which can take up to one week to provide results, could result in patient harm if treatment is delayed until the test results are available and many patients could be discharged from hospital by the time laboratory test results are available;
- Smaller hospitals serving remote and rural areas would experience problems accessing laboratory-based genotype testing;
- There are four regional genetic testing centres in Scotland and they are under pressure to deliver urgent cancer genetic testing priorities. There was concern that using regional genetic testing centres would result in inequalities in care across Scotland; and
- The Genedrive® CYP2C19 ID Kit had low test failure rate and can identify more targets, which is a crucial consideration for the inclusion of more patients from a wider range of ethnic backgrounds and therefore aids addressing inequalities in healthcare.

In addition, the Technology Assessment "*Genotype testing to guide antibiotic use and prevent hearing loss in neonates*" is for the Genedrive® MT-RNR1 ID Kit and concludes 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/

Dr Gino Miele, CEO of genedrive plc, said:*"Following positive recommendations by The National Institute for Clinical Care and Excellence (NICE) for both our MT-RNR1 and CYP2C19 ID products, we are delighted with these additional positive independent assessments of the SHTG, and look forward to further decisions of ANIA regarding potential national rollout plans in Scotland. We are proud to be at the forefront of near-patient pharmacogenetic testing and of the potential for our products to be significantly impactful in delivering improved patient outcomes in these vulnerable groups as well as offering significant savings to healthcare systems."*

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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.

About Clopidogrel

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

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.

About ANIA

Accelerated 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.

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