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

NICE recommends the Genedrive® CYP2C19-ID Kit
Genedrive® CYP2C19-ID test for genotype-guided clopidogrel treatment in the NHS chosen as the preferred platform for UK point-of-care genotype testing

genedrive plc (AIM: GDR), the point of care pharmacogenetic testing company, announces that the UK's National Institute for Health and Care Excellence ("NICE") has recommended in draft guidance that the Genedrive® CYP2C19-ID test should be used as the point-of-care ("POC") test of choice before clopidogrel administration in the management of Ischemic Stroke ("IS") and Transient Ischaemic Attack ("TIA") patients.

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, which are instrumental in the loss of metabolism function. The Genedrive® System automatically interprets the information for the clinician, allowing prompt administration of an optimised treatment plan.

According to the World Stroke Organization, there are over 77 million people globally who currently have experienced ischaemic stroke and it is estimated by the Stroke Association that there are 100,000 strokes in the UK each year. Suboptimal response to antiplatelet treatment following stroke is common, affecting about 20%-30% of patients in the general UK population, which increases to about 50%-60% in certain ethnic groups.

NICE recommended in the May 2023 draft guidance that people who have just had an IS or TIA should have a CYP2C19 genetic test prior to antiplatelet treatment. Following a public consultation of this draft guidance, which ends on 26 April 2024, final recommendations are expected to be published by NICE on 10 July 2024. The public consultation documents and summary review of NICE's information can be found at:
https://www.nice.org.uk/guidance/indevelopment/gid-dg10054/documents

The specialist NICE diagnostics assessment committee systematically reviewed the clinical and economic impact of genetic testing, including both laboratory-based and POC tests, concluding that it would be beneficial for people with loss-of-function CYP2C19 alleles to receive alternative antiplatelet treatment to clopidogrel and CYP2C19 genotype testing is also cost effective compared with not testing regardless of which alternative antiplatelet therapy people have.

In addition to being dominant in cost effectiveness models, NICE recommends the Genedrive® as the point-of-care platform of choice for CYP2C19 genotyping strategies in the NHS. The decision was based on several differentiating features of the Genedrive® technology; (1) its greater coverage of genetic variants compared to the other point-of-care system assessed, permitting increased equitable access to healthcare across ethnic populations, (2) no requirement for cold-chain storage logistics, (3) its ability to integrate with patient electronic healthcare systems.

As previously communicated, the Company's ongoing valued long-standing partnership with clinical genetics collaborators in Manchester under the DEVOTE programme will supplement our existing clinical performance data used for UKCA certification and lead to anticipated CE-IVD certification and commercialisation within the European Union, and those additional countries that recognise CE-IVD, in early 2025. Following the completion of the DEVOTE clinical performance, together with final NICE recommendation due on 10 July 2024, the Company would intend to actively pursue commercialisation in the UK.

James Cheek, CEO of genedrive plc, said: *"We are delighted to receive this recommendation from NICE for our CYP2C19 point of care pharmacogenetic test. The NHS has done significant work on both strokes and mini strokes, with campaigns for FAST (Face, Arms, Speech, Time) and promoting changing lifestyles to prevent a stroke. This guidance is just the next step in stroke management, ensuring that if you have a stroke, specifically related to a disruption of the blood flow, that the medicine given has a positive effect. Clopidogrel is the NICE recommended front line treatment for these types of strokes. However, if you are one of the estimated 20%-30% who are unable to metabolise Clopidogrel effectively you have the opportunity to be identified quickly and given an alternative medication. We are delighted to be part of this change which is in line with our strategy to deliver point-of-care pharmacogenetic testing to positively impact patient outcomes. With MT-RNR1 getting a NICE EVA conditional recommendation last year, further funding applied for to achieve a full recommendation this year, a strategy in place to achieve Food and Drug Administration ("FDA") approval and sales being realised from new customers in 2024 we feel there is growing momentum within the Group's POC pharmacogenetic testing strategy."*

Professor Bill Newman, Clinical Head of Division and Senior Lecturer in Clinical Genetics at Manchester University NHS Foundation Trust, said: *"The DEVOTE Programme funded by Innovate UK has brought together academic, industry and clinical partners from across Manchester to deliver novel genomic diagnostics to make medicine prescription safer and more effective for patients. We have been delighted to work with genedrive to develop their point of care test which will ensure that rapid results are available to reduce the risk of patients having further strokes."*

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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, simple to use and robust point of need pharmacogenetic platform for the diagnosis of genetic variations. This helps clinicians to quickly access key genetic information that will help them make the right choices over the right medicine or dosage to use for an effective treatment. Based in the UK, the Company is at the forefront of work on Point of Care pharmacogenetics. Pharmacogenetics looks at how your genetics impacts a medicines ability to work for you. Therefore, by using pharmacogenetics, medicines can be made safer and more effective. The Company has launched its flagship product, the Genedrive® MT-RNR1 ID Kit, which is a single-use disposable cartridge that circumvents the requirement for cold chain logistics by providing temperature stable reagent test kits for use on their proprietary test platform. This test allows clinicians to make a decision on antibiotic use within 26 minutes; ensuring vital care is delivered with no negative impact on the patient pathway.

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.