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

NICE recommends the Genedrive® CYP2C19-ID Kit in final guidance

Genedrive® CYP2C19-ID test chosen as the preferred platform for point-of-care genotype testing prior to clopidogrel treatment for stroke patients in the NHS

genedrive plc (AIM: GDR), the point-of-care pharmacogenetic testing company, is pleased to announce that following on from the draft guidance issued in April 2024, the UK's National Institute for Health and Care Excellence ("NICE") has recommended in its final guidance that CYP2C19 genotyping should be used to guide clopidogrel use after Ischaemic Stroke ("IS") or Transient Ischaemic Attack ("TIA"), and that the Genedrive® CYP2C19-ID test should be used as the test of choice for point-of-care strategies.

The guidance has been published today and can be found at:https://www.nice.org.uk/guidance/dg59.

With UKCA certification for the product already achieved, completion of the DEVOTE clinical phase, and today's final guidance from NICE recommending the Genedrive® CYP2C19 ID kit for use in point-of-care settings, the Company will now actively pursue commercialisation in the UK and Middle Eastern countries where device registration is enabled by UKCA certification, and is fully prepared to supply and meet the anticipated demand.

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

Whilst positioned primarily for enabling near-patient testing, the Genedrive® System is also suitable for traditional laboratory testing paradigms as a more affordable alternative to laboratory platforms where sample throughput requirements do not necessitate high-scale batch processing.

The specialist NICE diagnostics assessment committee systematically reviewed the clinical and economic impact of CYP2C19 genetic testing, including both laboratory-based and point-of-care

tests, concluding that CYP2C19 genetic testing strategies will be beneficial to people with loss-of-function CYP2C19 variants with alternative antiplatelet treatment and 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;

- its greater coverage of genetic variants compared to the other point-of-care system assessed, permitting increased equitable access to healthcare across ethnic populations;
- no requirement for cold-chain storage logistics and;
- its ability to integrate with patient electronic healthcare systems.

CE-IVD for CYP2C19-ID test

As previously communicated, the Company has an ongoing valued long-standing partnership with clinical genetics collaborators in Manchester under the DEVOTE programme, for which a key clinical milestone has been met for requirements for CE-IVD submission as announced in May 2024. This will supplement the Company's 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. Receipt of CE-IVD certification in addition to UKCA certification would enable the Company to penetrate markets which it estimates are worth in excess of £100 million per annum.

James Cheek, CEO of genedrive plc, said:*"We are delighted with this final guidance from NICE recommending implementation of CYP2C19 genotype-guided use of Clopidogrel in IS and TIA patients in the NHS to reduce risk of recurrent strokes, and recommendation of our CYP2C19 ID-kit as the point-of-care interventional platform of choice. This represents a key milestone in our commercialisation plans for the product, and further solidifies our business strategy of leading provision of cost-effective solutions for pharmacogenetics in time critical emergency healthcare situations. We are proud to be at the forefront of the emergence of near-patient genetic testing in emergency healthcare to facilitate optimal personalised therapeutic choices and ultimately improve patient outcomes."*

Professor Bill Newman, Professor of Translational Genomic Medicine at the University of Manchester and Lead of the NHSE Network of Excellence in Pharmacogenetics and Medicines Optimisation at Manchester University NHS Foundation Trust, said:*"To ensure that patients receive the correct treatment to reduce the risk of them having a further stroke after an initial episode, we need to use a rapid genetic test. The development of this new point-of-care diagnostic has the potential to significantly improve care for tens of thousands of patients after a stroke. As part of the DEVOTE project we have been delighted to have worked with genedrive to generate the evidence for this test to become available to patients."*

For further details please contact:

genedrive plc James Cheek: CEO / Russ Shaw: CFO	+44 (0)161 989 0245
Peel Hunt LLP (Nominated Adviser and Broker) James Steel / Patrick Birkholm	+44 (0)20 7418 8900

Walbrook PR Ltd (Media & Investor Relations)
Anna Dunphy

+44 (0)20 7933 8780
orgenedrive@walbrookpr.com
+44 (0)7876 741 001

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.
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About Stroke
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 people who have strokes in the UK each year[1], with these figures estimated to increase by 60% to 2035[2]. Globally, one in four people over the age of 25 will have a stroke in their lifetime, and there are 1.3 million stroke survivors in the UK[3], with current costs of care of approximately £26 billion[2]. Societal costs are expected to increase 250% over the period to 2035 unless measures to prevent strokes and reduce the disabling effects of strokes are successfully developed and implemented[2].

About Clopidogrel
Clopidogrel is an antiplatelet drug used in clinical management of stroke. It is metabolised into its active form by an enzyme encoded by the CYP2C19 gene which in some people has DNA variations that reduce the enzyme's function which means that clopidogrel does not work as well

in these people (Loss of function). Suboptimal response to clopidogrel is common, affecting up to 30% of patients in the general population, which increases to approximately 50%-60% in certain ethnic groups.

For dual antiplatelet therapy including clopidogrel, the UK National Clinical Guidelines for Stroke states that his should be considered in patients presenting within 24 hours of TIA and minor stroke[4].

1. https://www.stroke.org.uk/stroke/statistics
2. https://doi.org/10.1093/ageing/afz163
3. https://www.world-stroke.org/assets/downloads/WSO_Global_Stroke_Fact_Sheet.pdf
4. National-Clinical-Guideline-for-Stroke-2023.pdf (strokeguideline.org)

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