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

Genedrive® CYP2C19-ID Kit clinical performance published

Superior performance to laboratory test and alternative available point of care platforms

genedrive plc (AIM: GDR), the point of care pharmacogenetic testing company, announces that the clinical performance of its CYP2C19-ID Kit has been published in the Journal of Molecular Biology. The publication is available athttps://www.jmdjournal.org/article/S1525-1578(24)00312-X/fulltext.

Background to the Genedrive® CYP2C19 test

The Genedrive® CYP2C19 ID point of care genetic test is UK Conformity Assessed ("UKCA") certified and is recommended by The National Institute for Health and Care Excellence ("NICE") as the Point of Care ("PoC") test of choice for use in the NHS for CYP2C19 genotype guided prescribing of Clopidogrel in Ischaemic stroke (IS) and Transient Ischaemic Attack (TIA). It uses a single, non-invasive cheek swab sample, and rapidly identifies several important genetic variants of the CYP2C19 gene (Loss Of Function ("LOF")), which are instrumental in an individual's response to the antiplatelet drug clopidogrel which can be prescribed in Ischemic Stroke ("IS") and Transient Ischaemic Attack ("TIA"). Some of these important LOF variants are more prevalent in specific ethnic groups and are not included in targets in any other point of care CYP2C19 genotyping platform. The test reports CYP2C19 DNA variant information to the clinician and allows for prompt consideration of an alternative treatment plan for the circa 30% of individuals carrying CYP2C19 DNA variants which result in them being less likely to respond to clopidogrel.

Study Results

In the clinical study, CYP2C19 DNA variants in patients presenting in the acute emergency care setting were tested with the Genedrive® CYP2C19-ID test and results compared with those obtained by reference laboratory platform testing, with testing on a separate laboratory platform in instances where there was disagreement in test results.

In summary, in a cohort of 202 patients, in addition to being substantially less expensive than the laboratory platform, the Genedrive® CYP2C19 ID Kit outperformed laboratory testing with respect to (1) speed to result, (2) accuracy of LOF identification and (3) test fail rate. Sensitivity and specificity of the CYP2C19 ID Kit was 100%, with failure rate of 0.98% (three times lower than laboratory testing). In addition, the laboratory test platform returned incorrect results for eight samples (4%). Importantly, the Genedrive® CYP2C19 ID Kit identified seven patients harbouring LOF variants that would **not** have been detected using an alternative POC CYP2C19 genotyping platform which focuses on two specific LOF variants compared to five targeted by the Genedrive® test, or laboratory genotyping methods which also focus on these two LOF variants. Requirement for freezer storage of reagents of this alternative platform is also an implementation barrier in acute clinical settings that the Genedrive® technology circumvents.

This study confirms "that the Genedrive® System is able to provide an accurate, rapid, non-invasive alternative to standard laboratory testing and can be used as a point of care test in the clinical environment."

Gino Miele, CEO of genedrive plc, said:*"We are delighted with the clinical performance of our CYP2C19 ID Kit reported in this publication. With recommendation by NICE as the PoC test of choice for CYP2C19 genotyping in IS/TIA in NHS England, dominant health economic modelling by NICE, positive value assessment by the Scottish Health Technology Group, together with this study evidencing superior performance compared to laboratory testing and by extrapolation our nearest competitor product, we are well positioned to capitalise on the emerging clinical pharmacogenetics area of point of care CYP2C19 genotyped-guided clopidogrel treatment both domestically and internationally, ultimately enabling better patient outcomes, improving equitable access to healthcare and positively impacting healthcare financial burdens."*

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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.

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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].

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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