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

UKCA marking achieved for new Genedrive® CYP2C19 test

genedrive Point of Care test that helps manage treatment in stroke patients is now readying for NHS introduction

genedrive plc (AIM: GDR), the point of care molecular diagnostics company, announces it has achieved UKCA marking registration for its new Genedrive® CYP2C19 System. It is a point of care pharmacogenomic test that can differentiate between patients that could respond to clopidogrel treatment and those that will not, allowing more effective drug treatment to be prescribed on a personalised basis. The test can be performed at the bedside or in a ward, and can deliver a clinically actionable result in about one hour.

Poor response to treatment following stroke is common, effecting up to 30% of patients in the general population and in a recent report up to 50% in certain ethnic groups. In the UK, the National Institute for Health and Care Excellence ("NICE") recommended in May 2023 draft guidance that people who have had an ischaemic stroke or transient ischaemic attack ("TIA") should have a CYP2C19 genetic test prior to treatment. It's estimated that there are over 60 million ischaemic strokes per year globally and over 100,000 in the UK each year.

The Genedrive® CYP2C19 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 and poor activation of clopidogrel in a patient. The Genedrive® System automatically interprets the information for the clinician, allowing prompt administration of an optimised treatment plan. Like all genedrive products, the tests are presented in a temperature stable, freeze-dried format, allowing testing to be performed by healthcare workers, away from laboratory locations. In its performance evaluations, the test achieved 99% accuracy in detecting the variants that underpin loss of metabolism function.

UKCA marking now allows the Company to begin commercialisation in the UK, and actively engage in the DEVOTE programme (previously announced in May 2023), which will generate additional performance data in an acute care setting. This expanded dataset is required for CE marking submission, which will allow for commercialisation in the EU. Submission is expected in the first half of 2024 once genedrive's engagement with DEVOTE has completed. In the United Kingdom, the Company will be selling the product through its direct sales team, and momentum for adoption is expected to be influenced by positive final NICE recommendations for CYP2C19 testing, which are expected in December 2023.

David Budd, Chief Executive Officer of genedrive plc, said: *"UKCA marking of the Genedrive® CYP2C19 test is a milestone for the Company as we formally register our second pharmacogenomic test for use in emergency medicine. As we begin commercialisation and look to registration activities more globally, we will benefit from a rapidly evolving well documented clinical understanding and guidance for the use of genetic testing for stroke management. The use of point of care testing allows patients to be put on an optimised treatment plan as quickly as possible. The risk of recurrent stroke in the week after a TIA or minor stroke is up to 10%, so routine laboratory testing which can take many days or weeks is unlikely to be as appropriate as a point of care solution returning results in about one hour."*

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About genedrive plc (http://www.genedriveplc.com)
genedrive plc is a molecular diagnostics company developing and commercialising a low cost, rapid, versatile, simple to use and robust point of need molecular diagnostics platform for use in patient stratification (genotyping), pathogen detection and other indications in emergency care.

About DEVOTE
The Development and Validation of Technology for Time Critical Genomic Testing (DEVOTE) Programme is a collaboration between academics, clinicians, and industry partners. It aims to accelerate the adoption of genomic technology into clinical practice by supporting companies through each aspect of the translational pathway.

For more information contact info@devoteprogramme.com.