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

Key CYP2C19-ID test performance milestone achieved

genedrive plc (AIM: GDR), the point of care pharmacogenetic testing company, is pleased to announce that a key milestone has been met in The Development and Validation of Technology for Time Critical Genomic Testing ("DEVOTE") programme for its CYP2C19-ID kit. The programme has now passed the patient numbers required for a subsequent submission for an in vitro diagnostics CE certification ("CE-IVD"), which is still anticipated in early 2025.

The Genedrive® CYP2C19-ID point of care genetic test is UK Conformity Assessed ("UKCA") certified, 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 drug clopidogrel which can be prescribed in Ischemic Stroke ("IS") and Transient Ischaemic Attack ("TIA"). The test automatically interprets the CYP2C19 DNA variant information for the clinician and allows for prompt administration of an alternative treatment plan for the circa 30% of individuals that are less likely to respond favourably to clopidogrel.

DEVOTE is an all-comer study in which CYP2C19 DNA variants in patients presenting in the acute emergency care setting are tested with the Genedrive® CYP2C19-ID test and results compared with those obtained by reference laboratory platform testing, with testing on a third laboratory platform in instances where there is disagreement in test results. In the tests run to date the Genedrive® CYP2C19-ID test has out-performed the reference laboratory-based test with respect to coverage of LoF variants and accuracy (correct identification of variant).

The DEVOTE programme, through its lead partner the University of Manchester ("UoM"), has supported the Company's requirement for assessing performance in acute care patients and provided valuable supporting infrastructure to assess the real-world clinical performance of time-critical clinical tests in NHS settings. The study addresses clinical requirements of the In Vitro Diagnostic Medical Devices Regulation ("IVDR") for CE-IVD submission and subsequent commercialisation in those countries recognising CE-IVD, in addition to current UKCA certification allowing UK commercialisation.

Approximately 30% of patients in the cohort harboured CYP2C19 LoF variants as expected. The Genedrive® CYP2C19 test outperformed the laboratory test with respect to accuracy of identification of LoF alleles, and broader inclusion of LoF alleles. Genedrive® CYP2C19-ID test results are available in ~70 minutes.

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 test of choice in the NHS before clopidogrel administration in the management of IS and TIA patients (https://www.nice.org.uk/guidance/indevelopment/gid-dg10054/documents). The draft guidance is expected to be finalised on 10 July 2024.

James Cheek, CEO of genedrive plc, said: *"This study has been invaluable in progressing our requirements for CE-IVD certification to complement our existing UKCA certification. Our CYP2C19 test is the only one we are aware of that can deliver clinically actionable results for these DNA variants in the CYP2C19 gene in a rapid timeframe in emergency care settings at the point of care. We are excited that the availability of this intervention has the potential to make a difference to patients' lives and we look forward to working with UK stroke networks in the NHS to bring this vital test into day-to-day use."*

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: *"It has been very positive working with genedrive as part of the Innovate UK funded DEVOTE project to test clinical samples and determine how well the assay performs in this setting. It is clear that the test will offer an effective rapid*

the assay performs in this setting. It is clear that the test will offer an effective rapid solution to doctors and pharmacists to guide effective prescribing for patients with stroke."

Professor Ben Bridgewater, Chief Executive at Health Innovation Manchester, said: *"This is a great example of how the GM Health Innovation Accelerator programme is supporting development of our innovation ecosystem specifically in this case through validation of a novel and valuable rapid diagnostics test. Congratulations to genedrive for this achievement as they continue to collaborate with academic strengths in the city region to develop products to improve the health of our local population and address inequalities in care*."

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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 and is metabolised into its active form by an enzyme encoded by the CYP2C19 gene. The CYP2C19 gene in some people has variations that reduce the enzyme's function which means that clopidogrel does not work as well in these people (Loss of Function "LoF"). 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.

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