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

Genedrive® CYP2C19-ID Kit to be used to support expansion of use to include Acute Coronary Syndrome

genedrive plc (AIM: GDR), the point of care pharmacogenetic testing company, announces the use of the Genedrive® CYP2C19-ID Kit in a trial led by Manchester University Foundation Trust ("MFT") in collaboration with the Genotype Guided Primary Coronary Intervention ("GUIDE PCI") programme and the British Heart Foundation ("BHF") Centre of Excellence, which aims to assess the value and feasibility of rapid point of care CYP2C19 testing in cardiovascular disease to improve patient outcomes. The sales value of the order is circa. £120K.

CYP2C19 genotyping is already recommended by the National Institute for Health & Care Excellence ("NICE") prior to treatment with the antiplatelet Clopidogrel in Ischaemic Stroke ("IS") and Transient Ischaemic Attack ("TIA"), with the Genedrive® CYP2C19-ID kit recommended as the first line point of care test to be used in the UK NHS.

There are more than 7.6 million people living with a heart or circulatory disease in the UK, and over 100,000 hospital admissions each year due to heart attacks, with these patients often requiring lifelong antiplatelet therapy. The American Heart Association ("AHA") recently released a scientific statement recommending CYP2C19 genetic testing in cardiovascular indications such as Acute Coronary Syndrome ("ACS"), with an emphasis on results being available rapidly[1]. The GUIDE PCI programme at MFT aims to embed the Genedrive® CYP2C19-ID Kit into routine PCI clinical practice. Over a 12-month period, clinicians will use the Genedrive® CYP2C19-ID Kit for patients undergoing PCI, rapidly identifying which antiplatelet therapy they should receive. The programme will establish the feasibility and value of this intervention, supporting roll out at other centres.

Dr Gino Miele, CEO of genedrive plc, said:*"We are delighted that our CYP2C19 rapid genetic test is being assessed for use in ACS and PCI procedures in addition to current clinical recommendations by NICE for use prior to prescription of Clopidogrel in IS and TIA. With clinical recommendations for CYP2C19 genetic testing for IS, TIA and ACS, and with rapid genetic testing within 24 hours being recommended if clopidogrel is being considered, our CYP2C19 test is well positioned to enable this intervention and care pathway change, significantly improving patient outcomes whilst at the same time freeing healthcare resources and finances."*

Dr Jaydeep Sarma, Consultant Interventional Cardiologist in Greater Manchester, said:*"The Greater Manchester Regional Primary PCI service operates 24 hours a day, 7 days a week, 365 days a year. Thousands of patients are seen rapidly for life saving interventions from across the region each year and it's essential that their treatments are optimised as quicky as possible.*

Integration of this rapid test into routine practice means we can get patients on the right treatment the first time, improving outcomes for our patients and the service as a whole."

Professor Maciej Tomaszewski, Deputy Director at the British Heart Foundation Manchester Centre of Research Excellence, said:*"This is fantastic example of pharmacogenomics research in action, which has the potential to change clinical practice in cardiology clinics, wards and hospitals. The BHF Manchester CRE supports cardiovascular pharmacogenomics research and the follow up implementation programmes across the spectrum of cardiovascular diseases."*

Bill Newman, Professor of Translational Genomic Medicine at University of Manchester, Consultant in Genomic Medicine at MFT, and a researcher with the National Institute for Health and Care Research (NIHR) Manchester BRC, said:*"We're already seeing the impact of rapid genetic testing for patients who have had stroke or TIAs, with our colleagues in centres around the country telling us they need results quickly to inform their practice and avoid delays to discharge. The evidence bases for genotype guided antiplatelet therapy in cardiovascular disease is arguably even stronger than for patients who have stroke or TIA. The Guide PCI programme is a logical extension of our pharmacogenomics programme and reflects the regions commitment to personalised medicine."*

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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.

[1] https://www.ahajournals.org/doi/epdf/10.1161/CIR.0000000000001257

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