RNS Number : 9783Z
Genedrive PLC
12 August 2024

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

First UK commercial sales of the Genedrive® CYP2C19-ID Kit

genedrive plc (AIM: GDR), the point of care pharmacogenetic testing company, is pleased to announce that following the UK's National Institute for Health and Care Excellence ("NICE") final published 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[1], an initial order for the CYP2C19-ID Kit and instruments has been received (c.£0.1M) to support an implementation assessment at Greater Manchester's Comprehensive Stroke Centre ("CSC").

Hyperacute Stroke units ("HASU") are part of the UK's Integrated Stroke Delivery Network, where care typically covers the first 72 hours after admission, with the aim that every patient with acute stroke should gain rapid access to a stroke unit in under four hours and receive an early multidisciplinary assessment[2]. Greater Manchester CSC is the largest and busiest HASU in England with more than 2,000 stroke patient admissions per annum and is situated within the Manchester Centre for Clinical Neurosciences ("MCCN") at Salford Royal Hospital, part of Northern Care Alliance NHS Foundation Trust. The implementation assessment's aim is to establish the benefit for patients across Greater Manchester.

UK NICE guidance recommends laboratory CYP2C19 genotyping, and where not available or possible to implement point of care strategies, using the Genedrive® CYP2C19-ID test as the platform of choice. Whilst positioned primarily for enabling near-patient point of care testing, the Genedrive® System is also suitable for traditional laboratory testing paradigms as a more affordable alternative to more expensive laboratory platforms where sample throughput requirements do not necessitate high-scale batch processing.

Factoring in potential improvements in patient outcomes in addition to direct healthcare financial savings, implementation of CYP2C19 genotyping in IS/TIA has potential value to the NHS of approximately £91M and £454M over one and five years respectively[1].

Dr Gino Miele, CEO of genedrive plc, said:*"With recent NICE guidance recommending CYP2C19 genotyping strategies in the UK NHS for IS and TIA patients in the NHS who are eligible for receiving the antiplatelet Clopidogrel, and recommending our test as the point-of-care platform of choice, these initial first-sales of our CYP2C19 ID-kit in the UK to one of the largest stroke centres nationally is a key initial milestone in our CYP2C19 commercialisation strategy, and further strengthens our pharmacogenetic positioning strategy in emergency care more broadly. We look forward to increasing implementation of our CYP2C19 test in the UK NHS and internationally to the benefit of both healthcare systems financially and improvement of 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:*"We are delighted to work with genedrive to implement this new clinical test to ensure that patients following a stroke or a mini-stroke get onto the best treatment as soon as possible to prevent a further stroke."*

Dr. Natasha James and Dr. Kirsty Ward, Clinical leads for the Greater Manchester CSC, said:*"We are delighted to work with colleagues at Manchester Centre for Genomic Medicine and genedrive to bring the benefit of this novel technology to Stroke patients in Greater Manchester. The technology will help us to formulate a personalised optimal treatment plan for Stroke patients, that we hope will prevent future strokes and save lives."*

1. https://www.nice.org.uk/consultations/2556/1/recommendations

2. https://www.england.nhs.uk/wp-content/uploads/2021/05/stroke-service-model-may-2021.pdf

For further details please contact:

genedrive plc Gino Miele: 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 or genedrive@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.

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.

END

UPDUKOBRSAUWRAR