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

Genedrive® CYP2C19 ID Kit receives CE-certification under the European In Vitro Diagnostics Regulation

genedrive plc (AIM: GDR), the point of care pharmacogenetic testing company, announces the successful certification of its rapid CYP2C19 ID Kit genotyping platform under the European In Vitro Diagnostic Regulation ("IVDR") 2017/746. The IVDR replaces the In Vitro Diagnostic Directive ("IVDD") and is the current required regulatory basis for placing on the market, making available and putting into service any new In Vitro diagnostic medical devices within the European Union, with CE-IVD certification recognised for facilitating registration in several non-European countries.

Approximately 30% of individuals, and up to 56% in certain ethnic groups, carry DNA variants in the CYP2C19 gene which result in sub-optimal activity of the antiplatelet drug Clopidogrel, commonly prescribed in patients with serious cardiovascular events such as Ischaemic Stroke ("IS"), Transient Ischaemic Attack ("TIA") and Acute Coronary Syndrome, where patients with these variants who are prescribed Clopidogrel typically experiencing worse outcomes. The Genedrive® CYP2C19 ID Kit identifies five of these DNA variants, some of which are particularly important in certain ethnicities. It enables rapid identification of patients who are unlikely to respond to Clopidogrel, in time-critical emergency healthcare settings where rapid appropriate antiplatelet prescription is crucial.

The Genedrive® CYP2C19 ID Kit rapid test is best in class, recommended by the National Institute for Health and Care Excellence ("NICE") as the rapid genotyping platform of choice for use in the NHS, with dominant health economics, wider patient group coverage, and performance shown to be superior to laboratory testing methods.

Dr Gino Miele, CEO of genedrive plc, said: *"We are delighted to achieve this certification for our best-in-class CYP2C19 rapid genotyping platform. IVDR requirements have placed a heavy demand on Notified Bodies ("NB") responsible for ensuring compliance, and whilst certification of our Quality Management System and CYP2C19 ID kit under IVDR encountered a minor delay, it is noteworthy that this has still been achieved approximately six months earlier due to mitigation plans we put in place in August last year with respect to our NB.*

"Whilst UKCA certification enabled a focus on national commercialisation routes, including implementation into routine clinical use in NHS England's largest Hyper Acute Stroke Centre, and Middle East regions, we have also focussed efforts on defining market access routes in specific European countries which CE-certification now permits, and in non-European countries in which it facilitates registrations. Implementation of our rapid CYP2C19 platform has been estimated to potentially prevent c.3000 recurrent stroke admissions annually, whilst offering £160m of value, releasing 62,000 hospital beds and 230,000 healthcare professional hours in NHS England alone.

"These patient outcomes, financial and productivity gains are substantial and I am excited about the future impact of our solution to patients and healthcare systems both in the UK and internationally."

For further details please contact:

genedrive plc +44 (0)161 989 0245
Gino Miele: CEO / Russ Shaw: CFO

Peel Hunt LLP (Nominated Adviser and Broker) +44 (0)20 7418 8900
James Steel

Walbrook PR Ltd (Media & Investor Relations) +44 (0)20 7933 8780 or genedrive@walbrookpr.com

Anna Dunphy +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.