RNS Number : 6925W
Genedrive PLC
22 August 2022

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

NICE includes Genedrive CYP2C19-ID Kit in new Diagnostics Assessment Programme

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, announces that the UK's National Institute for Health and Clinical Excellence ('NICE') has commenced an evaluation of CYP2C19 genotype testing for Clopidogrel treatment, via a new NICE Diagnostics Assessment Programme ('DAP'). Genedrive's CYP2C19 ID Kit, currently in development, has been included in the assessment. Both of genedrive's new emergency Point of Care genetic screening tests are now included in new NICE reviews, following the MT-RNR1 DAP announcement on 16 June 2022.

https://www.nice.org.uk/guidance/indevelopment/gid-dg10054/documents

Clopidogrel is a drug that is given to ischemic stroke patients to prevent further clot formation. The CYP2C19 gene is involved in a metabolic pathway in the liver that converts Clopidogrel to its active form. Clopidogrel is less effective in individuals with certain genetic CYP2C19 variants because they do not metabolize Clopidogrel fully. As a consequence, it has a reduced impact on lowering the risk of a further stroke. Genedrive's CYP2C19 ID Kit, can provide guidance on which patients will respond to Clopidogrel. Patients with gene variants that result in reduced or loss of function of CYP2C19 can be given alternative treatments.

The Genedrive® CYP2C19 test is a simple, rapid point of care test, with no requirement for result interpretation and provides results in a clinically actionable timeframe. The genedrive test has been designed to have extended coverage across ethnic populations, which is important because the frequency of the various CYP2C19 related genetic changes differs across ethnicities.

David Budd, CEO of genedrive plc, said: *"We are pleased to be included as a participant in this latest NICE DAP programme. The review is very timely for us, given the current development of our new CYP2C19 ID Point of Care test. The clinical landscape for genotype-guided antiplatelet therapy has advanced in the last two years, with a growing number of pharmacogenetic clinical bodies recommending genotype-guided Clopidogrel administration. These guidelines and ongoing supporting factors such as this new NICE review serve to mature the market and ultimately can create a faster rate of adoption for new products such as our new Genedrive® CYP2C19 ID Kit."*

DAP evaluations are designed to provide robust recommendations on the use of new products, which is presented in the form of NICE guidance, and to promote rapid and consistent adoption of clinically innovative and cost-effective diagnostic technologies in the NHS. The DAP will assess the clinical and cost-effectiveness of Clopidogrel genotype testing, including any advantages of point of care testing vs central lab-based testing, in order to make recommendations on its use in the NHS.

The international CPIC guideline for Clopidogrel and CYP2C19 was recently updated (January 2022). The guidelines are based on clinical evidence and peer-reviewed literature. The clinical landscape for genetically guided anti-platelet therapy can be considered to be at a more advanced stage compared to many other genetic areas. Genedrive's new CYP2C19 Kit is targeted for completion in Q1 2023 and will require approval under the new IVDR regulations.

For further details please contact:

genedrive plc David Budd: CEO / Russ Shaw: CFO	+44 (0)161 989 0245
Peel Hunt LLP (Nominated Adviser and Joint Broker) James Steel	+44 (0)20 7418 8900
finnCap (Joint Broker) Geoff Nash / Kate Bannatyne / Alice Lane	+44 (0)20 7220 0500
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 molecular diagnostics company developing and commercialising a low cost, rapid, versatile, simple to use and robust point of need molecular diagnostics platform for the diagnosis of infectious diseases and for use in patient stratification (genotyping), pathogen detection and other indications. The Company has assays on market for the detection of MT-RNR1, HCV, certain military biological targets, and a high throughput SARS-CoV-2 assay. The Company recently released a point of care test for Covid-19.

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lseg.com or visit www.rns.com.

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our Privacy Policy.

END

MSCPPUGURUPPGMG