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

NICE recommends CYP2C19 genotyping for clopidogrel treatment

Genedrive® CYP2C19 ID test modelled to be a clinically and cost-effective option

genedrive plc (AIM: GDR), the point of care molecular diagnostics company, announces that the UK's National Institute for Health and Care Excellence ("NICE") has recommended in draft guidance that CYP2C19 genotyping should be used before clopidogrel administration in the management of ischemic stroke ("IS") patients.

The specialist NICE diagnostics assessment committee systematically reviewed the clinical and economic impact of genetic testing, including both laboratory-based and point-of-care ("POC") tests, concluding that CYP2C19 genetic testing strategies are likely to save costs and increase life expectancy compared with no testing. Screening patients to assess their clopidogrel resistance status allows for alternative treatments and better clinical outcomes.

Although the Genedrive® CYP2C19 ID test is in development, the NICE Committee included its predicted performance and pricing in its clinical and economic models and a thorough review is included in the Committee Papers in the public consultation documents. The Genedrive POC test had the highest probability of being the most cost effective for all scenarios compared to lab based or other POC solutions. Since final performance data for the Genedrive® CYP2C19 ID test is not yet available; and the product has not yet been registered in the UK under UKCA marking, the NICE Committee reasonably comments that no recommendation can yet be made for clinical use. The Company is anticipating UKCA marking of the Genedrive CYP2C19 test prior to NICE's final report, currently scheduled for October. At that time, NICE will have the option to update the recommendation on the Genedrive CYP2C19-ID Kit.

NICE's final guidance will follow the public consultation period which opens today, 19 May, and is scheduled to close on 9 June 2023. The public consultation documents and summary review of NICE's information can be found at: https://www.nice.org.uk/guidance/indevelopment/gid-dg10054/documents

David Budd, CEO of genedrive plc, said: "*This is the second time we have had the opportunity to work with NICE on recommendations for pharmacogenetic testing and I am pleased that they are very much in-line and supportive of our strategy in point of care pharmacogenomics for emergency care. The Company remains focused on achieving release and UKCA approval of the Genedrive CYP2C19 ID Kit in advance of the final NICE guidance publication date. Our product has a number of performance and workflow features including ready-to-go room temperature reagents, rapid turnaround time, extended genomic variant coverage and integration capability with hospital data management systems that will foster its adoption and uptake compared to alternatives.*"

POC has a key advantage over laboratory-based testing, providing results in one hour, which is useful in cases of transient ischaemic attack ("TIA") and minor stroke, due to the requirement for a result in less than 24 hours to commence correct treatment. Many lab-based tests return a result within 72 hours or longer. POC testing is thus an appropriate way to minimise or eliminate any period of potentially inappropriate treatment whilst awaiting results. There is also an advantage of POC in patients who have non-minor IS but cannot take aspirin.

There are approximately 100,000 strokes and 60,000 TIAs each year in the UK alone. Clopidogrel with aspirin is the most commonly prescribed antiplatelet medication used to reduce the risk of secondary events following a stroke or milder related conditions like IS. Clopidogrel is a pro-drug that requires conversion into an active form by an enzyme called CYP2C19. Genotyping of CYP2C19 allows targeting of more suitable treatment for the individual based on their personal metaboliser status.

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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.

About Clopidogrel

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 may not metabolise 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.

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