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

Breakthrough Device Designation received from the U.S. FDA

genedrive plc (AIM: GDR), the point-of-care pharmacogenetic testing company, is pleased to announce that it has received Breakthrough Device Designation from the U.S. Food and Drug Administration ("FDA") for the Genedrive® MT-RNR1 ID Kit.

The Genedrive® MT-RNR1 kit ("MT-RNR1 ID kit") is the world's first rapid point-of-care test to screen infants in an urgent care setting for a genetic variant that can cause life-long hearing loss when carriers of the variant are given certain antibiotics. Those infants identified by the Genedrive® MT-RNR1 ID kit as carrying the variant can then be given alternative antibiotics. It has the potential to save thousands of children from lifelong hearing loss, whilst providing a net positive financial outcome case to healthcare systems.

The Breakthrough Devices Program[1] is intended to provide patients and health care providers with timely access to medical devices by speeding up development, assessment, and review for premarket approval, 510(k) clearance, and *De Novo* marketing authorisation. Breakthrough Devices must meet the FDA's standards for device safety and effectiveness in order to be authorised for marketing.

Devices subject to premarket approval applications ("PMA"), premarket notification 510(k), or requests for *De Novo* classification request are eligible for Breakthrough Device Designation if the device meets FDA criteria that it "provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions", in addition to "there being No Approved or Cleared Alternatives" and "Device Availability being in the Best Interest of Patients".

The Breakthrough Devices Program offers manufacturers an opportunity to interact with FDA experts through several different programme options to efficiently address topics as they arise during the premarket review phase. This interaction can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritised review of their submission

In 2021, 3.7 million babies were born in the USA, with 10.5% born prematurely. It was estimated that malpractice litigation settlements in cases related to deafness caused by the use of aminoglycosides average over US$1.1 million per case, further adding to the positive health economic case of providing accurate and timely testing to reduce unwanted side effects of gentamicin usage. Extrapolating from UK figures, the Company estimates that approximately 1,000 babies per annum in U.S. Neonatal Intensive Care Units ("NICU") are at risk of aminoglycoside induced hearing loss.

genedrive intends to pursue the FDA *De Novo* regulatory pathway for entry into the U.S. market. The FDA *De Novo* pathway provides a vehicle for establishing new predicate devices that can reflect modern standards for performance and safety and can serve as a basis for future clearances. *De Novo* classification is a risk-based classification process used when there is a lack of a predicate device already cleared by the FDA.

James Cheek, CEO of genedrive plc, said: *"We are delighted to receive FDA designation of our MT-RNR1 point of care pharmacogenetic test and corresponding recognition of the potential benefits to U.S. patients. The U.S. is an attractive market for this unique test given the potential to save hundreds of individuals from life-long deafness and reduce litigation costs relating to the unwanted side effects from antibiotic use on those carrying the gene variant, and given its size, birth rates, use of diagnostic testing and reimbursement structure. The FDA Breakthrough Device Designation process will be invaluable in mitigating study design risks associated with bringing a novel test such as this to the U.S. market where no predicate device exists with which to align study designs to. Together with our in-place partnership with a multi-state physician led clinical partner with neonatal services expertise covering the majority of U.S. states we look forward to affordable, collaborative and timely progress through the FDA De novo process".*

[1] https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program

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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.

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