

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

Genedrive enters into a Clinical Trial Agreement with a leading multi-state physician organisation for clinical research studies of the Genedrive® MT-RNR1 Product Range in the USA

genedrive plc (AIM: GDR), the point of care pharmacogenetic testing company, announces that it has entered into a Clinical Trial Agreement with a leading multi-state physician organisation ("Research Partner") in the USA to support clinical studies required for engagement with the U.S. Food and Drug Administration ("FDA") to progress the regulatory approval of the Genedrive® MT-RNR1 ID Kit into the USA via the FDA *De novo* submission process.

In 2021, 3.7 million babies were born in the United States, with 10.5% born prematurely¹. It has been estimated that malpractice litigation settlements in cases related to deafness caused by the use of aminoglycosides average over US\$1.1 million per case², further adding to the positive health economic case of providing accurate and timely testing to reduce unwanted side effects of gentamicin usage.

The Genedrive® MT-RNR1 ID Kit is the world's first point-of-care genetic test to reduce the risk of antibiotic induced hearing loss (AIHL). Following detection of the MT-RNR1 variant an alternative antibiotic treatment can be prescribed. 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 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 predicate device already cleared by the FDA. Our partnership enables affordable access for clinical studies in NICU sites in the United States as required for the FDA *de novo* submission process, with a leading multi-state physician organisation with expertise and coverage of US neonatal services.

James Cheek, CEO of genedrive plc, said: *"I am delighted with this agreement to progress our aim of introduction of our MT-RNR1 point of care pharmacogenetic test to the U.S. The U.S. is a particularly 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. Additionally, the U.S. Market is potentially the most attractive market given its size, birth rates, use of diagnostic testing and reimbursement structure. As already announced genedrive will be seeking funding to progress the required clinical studies."*

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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, simple to use and robust point of need pharmacogenetic platform for the diagnosis of genetic variations. This helps clinicians to quickly access key genetic information that will help them make the right choices over the right medicine or dosage to use for an effective treatment. Based in the UK, the Company is at the forefront of work on Point of Care pharmacogenetics. Pharmacogenetics looks at how your genetics impacts a medicines ability to work for you. Therefore, by using pharmacogenetics, medicines can be made safer and more effective. The Company has launched its flagship product, the Genedrive® MT-RNR1 ID Kit, which is a single-use disposable cartridge that circumvents the requirement for cold chain logistics by providing temperature stable reagent test kits for use on their proprietary test platform. This test allows clinicians to make a decision on antibiotic use within 26 minutes; ensuring vital care is delivered with no negative impact on the patient pathway.

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.

1 <https://www.cdc.gov/nchs/data/vsrr/vsrr020.pdf>

2 <https://aao-hnsfjournals.onlinelibrary.wiley.com/doi/10.1177/0194599814536850>

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