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

Genedrive file US FDA Pre-Submission for the Genedrive® MT-RNR1 Product Range

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, announces that it has commenced 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.

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

genedrive has submitted via the FDA's Pre-Submission process ("Pre-Sub") because there is no exact comparable test in the market already. The Pre-Sub process allows the Company an opportunity to clarify its testing and validation approach, confirm the appropriate regulatory application pathway (510(k) vs *De Novo* application) and gain additional procedural feedback from the FDA with the aim of making the final submission process more efficient.

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.

David Budd, CEO of genedrive plc, said: *"The US 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. Either an FDA 510(k) clearance or the granting of a De Novo request is required to allow us to market this test in the US. Ultimately, we feel that the US market is potentially the most attractive market given its size, birth rates, use of diagnostic testing and reimbursement structure."*

A 510(k) is a premarketing submission made to the FDA to demonstrate that the device to be marketed is safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to premarket approval (PMA). The *De Novo* pathway provides a vehicle for establishing new predicates 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.

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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. The Company has assays on the market for the detection of MT-RNR1, HCV, certain military biological targets, a high throughput SARS-CoV-2 assay and a point of care test for Covid-19.