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

NIHR and OLS Funding Package to address NICE Real World Evidence Generation Requirements for the Genedrive® MT-RNR1 ID Kit
Revenue of £500k over the life of the award

genedrive plc (AIM: GDR), the point of care Pharmacogenetic testing company, announces a successful funding award to its clinical partners from the National Institute for Health and Care Research ("NIHR") in collaboration with the UK Government Office for Life Sciences ("OLS") to address evidence generation requirements of the National Institute for Health and Care Excellence ("NICE") Early Value Assessment ("EVA") for the Genedrive® MT-RNR1 ID kit.

The NIHR/OLS Real World Evidence Programme is aimed specifically at technologies like the Genedrive® MT-RNR1 ID kit which have been recommended for use in the NHS via the NICE EVA, to enable the addressing of real-world evidence gaps and the potential subsequent provision of a full (non-conditional) recommendation by NICE to accelerate the widespread adoption and implementation into the NHS.

The programme is clinician consortia-based and will be led by principal investigators Professor Bill Newman and Dr. John McDermott (University of Manchester / Manchester University NHS Foundation Trust), with 14 separate hospital Neonatal Intensive Care Units across England (inclusive of some sites which have already implemented the Genedrive® MT-RNR1 ID test as part of routine clinical use), Scotland, Wales and Northern Ireland (inclusive of nine sites already utilising the Genedrive® MT-RNR1 ID test in routine clinical practice). The start date was 1 November 2024 with a maximum duration of 18 months, with sites phased into group 1 (sites already currently using the test) and group 2 (remaining sites). Group 1 site testing is funded under the programme for six months from project initiation, following which funding for continuity of routine clinical practice will be required to be sought from alternative sources by those sites.

Revenue to Genedrive for the MT-RNR1 ID kit under the programme is expected to be approximately £500,000.

Whilst scheduled for a maximum of 18 months, performance data can be submitted to the NICE EVA Evidence Generation team at an earlier point if the team believes the evidence generation requirements have been successfully fulfilled. Performance data generated during the programme is also expected to contribute towards clinical performance data requirements for FDA as part of planned *De novo* submission process required for commercial entry into the U.S.

Gino Miele, Chief Executive Officer of genedrive plc, said: *"We are delighted with this funding package award to our clinical collaborators, representing a key step in enabling generation of real world evidence data requirements of NICE to transition from conditional to full recommendation. The programme will run in parallel with, and be complementary to, our continued sales expansion, nationally and internationally. The goal of NIHR and the Government's Office for Life Sciences via this programme is to drive adoption and implementation of innovative technologies such as ours into the UK's NHS, to drive improved patient outcomes and economic benefits."*

For further details please contact:

genedrive plc Gino Miele CEO / Russ Shaw: CFO	+44 (0)161 989 0245
Peel Hunt LLP (Nominated Adviser and Broker) James Steel / Patrick Birkholm	+44 (0)20 7418 8900
Walbrook PR Ltd (Media & Investor Relations) Anna Dunphy	+44 (0)20 7933 8780 orgenedrive@walbrookpr.com +44 (0)7876 741 001

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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