FDA Grants Breakthrough Device Designation to DNAe's Sequencing Diagnostic

London, UK and Carlsbad, CA, USA – 9 April 2020 – DNAe, the next generation sequencing company developing novel diagnostics for use at the point-of-need, today announced that the US Food and Drug Administration (FDA) has granted it a "Breakthrough Device" designation for its pioneering platform and first assay.

DNAe has reinvented sequencing in order to develop a compact device operable by non-specialist users. LiDia-SEQ™ will, for the first time, bring genomic analysis into use at the point-of-need to meet urgent medical needs. The entire process is automated, from raw sample through to actionable report, in a cartridge-contained, hands-free format, and can be used in diverse environments. The platform is based on novel, semiconductor sequencing, which uses a silicon chip to detect ions released in the step-by-step construction of nucleic acids, e.g. DNA.

The device will support a pipeline of rapid and cost-effective tests, including for infectious disease diagnostics, cancer, infection control, and preparedness and response for pandemics. In 2016, DNAe was awarded a contract with the Biomedical Advanced Research and Development Authority (BARDA*), worth up to $51.9 million if all options are awarded, to support development of the innovative platform initially for rapid diagnosis of antimicrobial resistant infections.

Now, the FDA has granted DNAe a Breakthrough Device designation for LiDia-SEQ™ and its first assay. This first assay is in infectious disease, a groundbreaking direct-from-specimen test for bloodstream infections (BSI) and antimicrobial resistance (AMR) to detect and identify infections that can lead to sepsis.

This diagnostic is poised to revolutionize treatment, particularly of antibiotic resistant infections, addressing a critical unmet need. By rapidly detecting and identifying infectious agents and the most prevalent AMR markers directly from whole blood specimens, the platform will enable swifter treatment with targeted therapeutics, improving patient outcomes. The prototype assay currently under development consists of >1000 bacteria, 150 fungi/yeast and 35 AMR markers. The Company reported successful completion of the first phase of development in 2018 and is now approaching completion of the second phase.

A 'Breakthrough Device' is a device that provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions. Under the program, the FDA will provide frequent and informal interactions and support during the advancement of DNAe's LiDia-SEQ™ sequencing system and BSI/AMR test, from development to launch.

Samuel Reed, President of DNAe commented: *"We are proud that the FDA has decided to grant Breakthrough Device designation to our LiDia-SEQ™ sequencing system and BSI/AMR test. This is testament to the growing recognition of the profound benefit our technology can offer to clinicians and patients. We look forward to working with the FDA and expediting development of our diagnostic to market."*

Professor Christofer Toumazou, DNAe's Executive Chairman and founder, and Regius Professor of Engineering at Imperial College London added: *"At a time when health systems are under acute pressure to deliver a rapid response to infectious agents, the vital need for improved diagnostic technologies is self-evident. DNAe's direct-from-specimen sequencing technology can quickly identify infectious agents and AMR, providing insightful and actionable information to clinicians. By enabling the right treatment at the right time, we can help to save patient's lives."*

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About DNAe – www.dnae.com

DNAe is commercializing its pioneering semiconductor sequencing technology for healthcare applications where rapid point-of-need diagnostics are of critical need. It is developing LiDia-SEQ™, a user-friendly, direct-from-specimen platform that performs genomic analysis on a microchip, to provide actionable information to clinicians.

DNAe's initial focus is on infectious disease diagnostics, where speed and DNA-specific information can make the difference between life and death. This includes a range of tests, starting with a groundbreaking test for bloodstream infections (BSI) and antimicrobial resistance (AMR), which uses whole blood specimens to detect and identify infections that lead to sepsis. This will provide clinicians with actionable information to help select the appropriate antibiotics to treat the disease. A pipeline of follow-on tests are in development for viruses and cancer testing and monitoring.

The Biomedical Advanced Research and Development Authority (BARDA), a division of the Assistant Secretary for Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS), awarded DNAe a contract worth up to $51.9 million, if all options are awarded, to develop its diagnostic platform, initially for antimicrobial-resistant infections.

A private company, with facilities in London, UK and Carlsbad, CA, USA, DNAe has strong financial backing from its investors, including major shareholder Genting Berhad, a Malaysian-based global investor with a growing portfolio of cutting-edge life sciences companies.