



Breakthrough in Rapid Diagnostic for Antimicrobial Resistance

DNAe achieves major milestone in a novel clinical sequencing platform, successfully completing the first phase of its \$51.9 million contract with US government's BARDA

London, UK and Carlsbad, CA, USA – 2 November 2018 – A rapid new diagnostic platform that harnesses the power of semiconductor DNA sequencing, promises to revolutionise the ability of physicians to treat antimicrobial resistant infections.

DNA Electronics ('DNAe'), the company behind the platform, today announces that it has successfully completed the first phase of its contract that could be worth up to \$51.9 million, with U.S. government agency, the Biomedical Advanced Research and Development Authority (BARDA)*. The contract, initially awarded in September 2016, supports the development of DNAe's next generation sequencing (NGS) platform for rapid diagnosis of antimicrobial resistant infections and influenza. BARDA has already approved the next stage of the contract, which is currently underway.

Using technologies that will ultimately be suitable for a rapid user-friendly test, DNAe has successfully sequenced the DNA of bacteria directly from an unprocessed blood sample. This has not been possible with any sequencing technologies to date, which have typically entailed long turnaround times and been relegated to specially-trained users in sophisticated labs. This breakthrough will enable hospitals to precisely identify the infectious agent and any resistance to antibiotics. This intelligence is vital, helping physicians choose targeted treatments that will be most successful in treating the infection.

"This will help to address the increase in antimicrobial resistance by fundamentally changing the way antibiotics are prescribed" said Professor Chris Toumazou, the inventor of semiconductor sequencing technology, DNAe's Executive Chairman and Regius Professor of Engineering at Imperial College London (Department of EEE). He added *"The relative speed, simplicity, scalability and cost-effectiveness of semiconductor sequencing allow it to be used in a much wider range of settings than previously possible for DNA sequencing, and make it particularly suited to application in diagnosis."*

Sam Reed, President, U.S. Office said: *"We have completely redesigned the DNA sequencing process to allow it to be used for rapid diagnosis in hospitals, closer to the patient, and operated by users who are not specially-trained. It's a completely different type of workflow than has been used before, so successfully achieving this latest milestone was a real 'eureka moment'. We now have proof that this new approach works – all we need to do is integrate the steps into one box. BARDA's support is enabling us to fast track this program and address the global crisis of antimicrobial resistance."*

BARDA has already approved DNAe to progress to the second phase of the contract, releasing \$10.98m for the development of an alpha prototype. DNAe has also increased its engagement with clinicians and end users, having brought on board an expert clinical advisory board in 2017.

Each year in the United States alone, at least 2 million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die each year as a direct result of these infections.¹ In addition, across Europe, an estimated 25,000 people die each year as a result of hospital infections caused by antibiotic resistant *Escherichia coli*, *Klebsiella pneumoniae*, *Enterococcus faecium*, *Pseudomonas aeruginosa* and methicillin-resistant *Staphylococcus aureus* (MRSA), adding over £1 billion to hospital treatment and societal costs. The problem is

getting worse and unless tackled antibiotic resistance could result in 10 million deaths per year globally by 2050, costing an estimated £66 trillion.²

Dr Steve Allen, CEO DNAe Group Holdings commented, *“Our next-generation sequencing-based diagnostic platform has been carefully designed with the end users in mind, and we have been interacting with clinicians from the outset to get feedback at every stage of development to make sure it meets their needs. We are realising our vision of bringing DNA sequencing into the clinic, so that patients can really benefit from its accuracy and speed of diagnosis which should make such a difference to getting the most effective treatment to patients.”*

DNAe’s genomic analysis technologies are based on its invention of semiconductor DNA sequencing, a specific type of next-generation sequencing that works by using a silicon chip to detect the ions released as a DNA strand is built up molecule by molecule. DNAe has three new patent applications from the first phase of the project alone.

Professor Chris Toumazou concluded that, *“Bringing genomics and DNA sequencing closer to the patient will transform the treatment pathway by arming doctors with the information that they need to make an evidence-based treatment decision. The continued support of BARDA will be instrumental in our mission to provide rapid diagnostics to support healthcare professionals globally.”*

*BARDA is a division of the Assistant Secretary for Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS).

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About DNAe – www.dnae.com

DNAe is commercializing its pioneering semiconductor DNA sequencing technology for healthcare applications where rapid near-patient live diagnostics is needed to provide actionable information to clinicians, saving lives by enabling the right treatment at the right time.

In January 2015 DNAe acquired nanoMR, Inc. (now DNA Electronics Inc.), a developer of a novel system for rapid isolation of rare cells in the bloodstream. DNAe is developing LiDia[®], its sample-to-result genomic analysis platform, combining DNA Electronics Inc.’s Pathogen Capture System with its own portfolio of semiconductor-based genomic technologies, trademarked Genalysis[®]. The LiDia[®] range of tests will enable DNA analysis directly on a microchip, providing rapid and accurate results from a user-friendly system.

DNAe’s initial focus is on infectious disease diagnostics, where speed and DNA-specific information can make the difference between life and death. LiDia[®] launches with the LiDia[®] Bloodstream Infection (BSI) test, a ground-breaking rapid direct-from-specimen test for bloodstream infections that lead to sepsis. Built into a compact device for use at the point of need, the system will diagnose accurately and rapidly what infection a patient has, providing the clinician with actionable information to help select the appropriate antibiotics to treat the disease.

In October 2016, 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 to develop Genalysis[®] for rapid diagnosis in two key applications; antimicrobial resistant infections and pandemic influenza.

A private company, with bases 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.

References

1. US Centers for Disease Control and Prevention website.
<https://www.cdc.gov/drugresistance/threat-report-2013/index.html>
2. UK Government Health matters antimicrobial resistance website.
<https://www.gov.uk/government/publications/health-matters-antimicrobial-resistance/health-matters-antimicrobial-resistance>

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