Rapid Detection of Pathogen and Antibiotic Resistance with DNAe's LiDia® Bloodstream Infection (BSI) Technology

- Data presented at 28th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Madrid, Spain
- DNAe's LiDia® BSI method accurately detected pathogen and antibiotic resistance in samples collected from patients receiving antibiotic therapy
- Pathogen detected in 9 samples that were negative in the paired blood culture but confirmed with other microbiological data
- Time from specimen collection to result for the LiDia® BSI method was just a few hours, compared to 2-5 days with blood culture
- Study conducted in collaboration with Mayo Clinic and University New Mexico Health Sciences Center

London, UK and Carlsbad, CA, USA – 24 April 2018 – DNAe, the inventor of semiconductor-based genomic analysis technologies, and the developer of a new game-changing test for bloodstream infections (BSI) that can lead to sepsis, announces new data generated with its LiDia® Bloodstream Infection (BSI) technology, currently in development. The LiDia® BSI method was demonstrated to detect pathogen and antibiotic resistance in samples collected from patients after receiving antibiotic therapy. Time to detection by the LiDia® BSI method was significantly shorter (hours vs. days) compared to standard-of-care blood culture testing.

Early treatment with broad-spectrum antibiotics is critical for patients with BSIs. However, antibiotics can affect the growth of any bacteria present in a sample and can therefore lead to false negatives if blood culture is used for diagnosis once a patient has begun antibiotic treatment. The technology used by LiDia® BSI can detect the presence of pathogens without interference by antimicrobial therapy.

Pathogens and antibiotic resistance detected by the LiDia® BSI method in samples collected from patients with suspected or confirmed BSI showed concordance with blood culture results in 31 patients pre-treated with antibiotics. The LiDia® BSI method also detected pathogens in a further nine samples, where blood culture collected concurrently produced a negative result. The LiDia® BSI results in these samples matched earlier blood culture results from the same patients. Time to result for the LiDia® BSI method was just a few hours, whereas blood culture results were available 2-5 days after specimen collection.

Clinical specimens were collected with consent from two sites, the Mayo Clinic (Rochester, MN, USA) and the University of New Mexico Health Sciences Center (Albuquerque, NM, USA). The largest numbers of patients with positive blood cultures in the DNAe study came from the Medical Intensive Care Unit (MICU) (25%), surgical wards (20%) and general medical wards (17.5%), followed by Emergency Departments (ED) (12.5%). The most frequently encountered microorganisms were *Escherichia coli*, *Staphylococcus aureus* and *Klebsiella pneumoniae*.

Once a specific diagnosis is confirmed, patients can be treated with a more targeted antibiotic. Rapid and accurate identification of the pathogen would enable physicians to prescribe targeted treatment faster, potentially improving the patient's prognosis and reducing healthcare costs. It could also help

to reduce the spread of antimicrobial resistance by preventing the over-use of broad spectrum antibiotics.

David Davidson, Chief Scientific Officer at DNAe and author on the poster said, "The study demonstrates the real-world potential of LiDia® BSI, and its ability to rapidly identify infectious agents even in patients who are already being treated with antibiotics. The test could help clinicians determine if patients already being treated with antibiotics are on the correct drug and may enable treatment with targeted antibiotics to begin immediately. Faster and more tailored treatment with this test could have huge implications for patient care."

The data were presented as a poster (#P1960) at the 28th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), in Madrid, Spain, 21-24th April, 2018. Whilst the data presented at ECCMID combined LiDia®'s core methodologies, prototype systems were on show at ECCMID, demonstrating the simple, rapid utility of the test, at the point-of-need.

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About DNAe – www.dnae.com

DNAe is developing 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® will launch with the LiDia® Bloodstream Infection (BSI) test, a groundbreaking 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.

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.

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