PRESS RELEASE

World’s Fastest Sepsis Test from Abionic Produces Result in Five Minutes when Tested in patients at London and Zurich Hospitals

- The UK National Institute for Health and Care Excellence (NICE) is urging hospital staff to treat people with life-threatening sepsis symptoms within one hour
- University College London Hospitals (UCLH) evaluation highlighted that the 5 minutes abioSCOPE is perfectly adapted for use as a near-patient testing platform for accelerating time to results in hospitals
- Sepsis in burn patients identified 24 hours before clinical symptoms in Zurich Hospital Intensive Care Units (ICU)
- CE marked abioSCOPE PSP test to help assess the risk of sepsis in Emergency Rooms (ER) and ICU available for sales in Europe by the end of 2018

Lausanne, Switzerland, May 31, 2017 – Abionic SA, a developer of disruptor nanotechnology based point-of-care diagnostic solutions, announced today initial positive results from evaluation studies with its rapid PSP test for sepsis risk assessment and management conducted at two internationally renowned university hospitals, Zurich University Hospital (Switzerland) and University College London Hospital (UK). Sepsis is the number one preventable death, if treated within the first hour. Abionic’s CE marked, abioSCOPE is the only device worldwide that provides results showing an indication of sepsis within 5 minutes.

“Accurately diagnosing sepsis early is crucial so that appropriate treatment can be started. This provides the greatest chance of success and patient recovery. These initial clinical evaluation studies have demonstrated the potentially huge impact our five minute test can have in hospital ICUs and emergency departments,” stated Dr. Fabien Rebeaud, Chief Scientific Officer of Abionic.

In the Zurich University Hospital study, measurement of PSP with the abioSCOPE was conducted daily for up to 8 days in a panel of ICU patients, with results blinded to the treating clinicians. Retrospectively, PSP values and medical records of the patient were compared. The data obtained suggested that a raise in the PSP value was observed in up to 24 hours before the apparition of clinical symptoms of sepsis. Moreover, a rapid return of the PSP value to baseline was also observed during the course of the antibiotic therapy. The abioSCOPE PSP test could therefore be used by doctors
to initiate antibiotic treatment earlier as well as to monitor for effectiveness of therapy.

“Pancreatic stone protein (PSP) is currently one of the most promising biomarkers to identify sepsis patients early. A precise and accurate sepsis biomarker makes sense only if it is readily available to the clinicians, and as seen from the data generated in our recently completed study, the 5 minute abioSCOPE platform is unique to provide this service,” said Professor Dr Rolf Graf, Head of Research, Department of Surgery and Transplantation, Zurich University Hospital.

University College London Hospital (UCLH) hosts one of the largest critical care unit in the UK (44 beds, 3000 patients per year). The evaluation of the PSP test in this unit is currently ongoing. To date, 15 patients within a week have been evaluated, with results confirming that the abioSCOPE is a well-designed, point of care (POC) diagnostic platform for use in ICU, typically next to a blood gas analyser.

“This POC test has the potential to help us identify sepsis patients more quickly than with currently available technologies. Introducing such a test complies with recently released NICE objectives as well as the guidelines issued earlier this year by the World Health Organisation (WHO),” said Dr Niall MacCallum, Leader of the Critical Care Clinical Trial Team at UCLH.

Abionic is currently preparing an international clinical studies in over 200 ICU patients to evaluate the efficacy of the abioSCOPE PSP test to help clinicians in identifying and managing patients at risk of sepsis and septic shock. Long-term, Abionic believes this test could be used in emergency departments:

- for triage risk stratification
  - discharge
  - observation in intermediate care unit
  - immediately send to ICU
- aid in taking the decision to start antibiotic treatment
  - optimization of antibiotic treatment is key to battle antibiotic resistance, a major healthcare problem worldwide

Hosted by the Global Sepsis Alliance, jointly with the German Ministry of Health and the International Alliance of Patients’ Organizations, the World Health Assembly Side Event on Sepsis brought together key opinion leaders active in the sepsis field. During the event, the General Assembly has recognized sepsis as a health priority and adopted the WHO resolution to fight sepsis. The event was held on May 24th, in Geneva. Dr. Fabien Rebeaud participated in the event.

abioSCOPE PSP (sepsis risk assessment and management test)
According to clinical studies, pancreatic stone protein (PSP) is a very promising biomarker to aid in identifying patients at risk of sepsis, with a sensitivity and specificity superior to other biomarkers currently used, such as CRP, PCT and white cell blood count. However, measuring this information can only be helpful if it is rapidly and easily available to clinicians. The abioSCOPE can measure PSP in five minutes at the point-of-care, with high sensitivity and selectivity. A good comparison has been observed between the PSP measured values in an ELISA microtiter (industry standard) and the abioSCOPE over a wide dynamic range (3 to 400 ng/ml). The resulting data enables clinicians to take the best, potentially life-saving decision for the benefit of the patient.

Sepsis is the most common causes of mortality in intensive care units. It is a syndrome characterized by an overwhelming systemic response to infection, which can rapidly lead to vital organ dysfunction, and death. Sepsis accounts for 40% of total ICU expenditure and every year, 18 million individuals worldwide die from sepsis. Early diagnosis and management of sepsis greatly improves chances of survival and mitigates the risk of suffering from severe, long-term, complications.

About the abioSCOPE®
The abioSCOPE is a CE Marked, medical device that provides rapid diagnostic test results. The instrument is composed of a fully automated fluorescent microscope, a mounting plate (the abioDISC), onto which is placed a single-use disposable IVD CAPSULE. Following preparation, the sample is placed into the IVD CAPSULE and the abioDISC is inserted into the abioSCOPE, in the same way that a DVD is inserted into a player. In a few minutes the results are then presented on a high-resolution touch screen and saved onto a SD card provided by Abionic. The abioSCOPE can be used by any healthcare professional and does not require extensive training.

About Abionic
Abionic has developed and commercialized abioSCOPE, a rapid point of care diagnostic platform to improve medical diagnosis. This revolutionary nano-technology-based test system provides healthcare professionals with tools that help them to make a diagnosis from a single drop of patient’s blood. The first abioSCOPE applications are in allergy. Abionic already commercializes a test measuring total IgE and one used to detect the five main respiratory allergens.

Abionic products, such as the abioSCOPE (the reader), the tests containing nanofluidic sensors and the abioGUIDE (the application for smartphones and tablets) have been developed and assembled within the company.

Founded in 2010, Abionic developed its nanotechnology within the Swiss Federal Institute of Technology in Lausanne (EPFL). For further information, visit www.abionic.com.
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