PRESS RELEASE

Abionic integrates first patients in US clinical trial for sepsis diagnosis method

Biopôle, Lausanne, Switzerland, 9th January 2020 – Abionic SA, Swiss Medtech firm based in Lausanne, is initiating a pivotal clinical trial in the US for an innovative point-of-care diagnostic method for sepsis to validate the results of a first trial that took place in Europe in 2019, proving the suitability of Abionic's sepsis test on the abioSCOPE® device to identify sepsis. The PSP test on the abioSCOPE® can diagnose sepsis 24 hours earlier than today's standard of care for sepsis diagnosis. For the US version of the study, the first patients are now being integrated.

The study will be held in seven leading hospitals: Rhode Island Hospital in Providence, RI, Baystate Medical Center in Springfield, MA, Rush Medical University in Chicago, IL, and the Mercy Health clinics Saint-Vincent, Saint-Anne, and Saint-Charles, all located in Toledo, OH. The trial will support an FDA 510(k) filing. The goal of the study is to assess the performance of immunoassay measurements of pancreatic stone protein (PSP) performed on Abionic's abioSCOPE® device. As indicated by earlier studies, PSP is the best marker to distinguish sepsis from non-infectious inflammation. The US study therefore seeks to confirm the results of the previously conducted European trials that found the PSP test on the abioSCOPE® is able to recognize sepsis earlier than other markers.

"We are enthusiastic about this study and the initiation of the recruitment", commented Dr. Luis Jauregui, Investigator at St. Vincent Medical Center in Toledo, Ohio, where the first patient of the study has been enrolled. "This study is well designed to provide important clinical evidence on the performance of the PSP test on the abioSCOPE® device for the diagnosis of sepsis and our clinical research institution is pleased to contribute to it"

Prof. Dr. Mitchell Levy, Medical Director of the Medical Intensive Care Unit at Rhode Island Hospital in Providence, RI, adds: "Early recognition of sepsis is key, but current biomarkers are of limited help. We believe that the PSP is a promising marker that could help us identify and treat sepsis better than today and we look forward to seeing the results of this study."

Of the 30 million people that are affected by sepsis each year, nine million cases are fatal. Unfortunately, sepsis symptoms are often unclear and unspecific. This results in sepsis being overlooked or recognized too late, as mortality increases by ~ 8% per hour the treatment is delayed. Current methods can take up to 48 hours to diagnose sepsis, meaning that vital time is lost, and survival chances diminish. Moreover, sepsis is also extremely costly for healthcare organizations: in the US alone, sepsis-related costs in hospitals surpass $24 billion annually.

abioSCOPE® delivers results in as little as five minutes, allowing immediate administration of effective treatment and thus reducing mortality.This also allows for lower costs for healthcare organizations.

"At Abionic we are committed to providing innovative solutions across the globe to help healthcare practitioners recognize sepsis earlier to treat the condition before it's too late. The trial we are initiating is an important step toward bringing our sepsis test on the abioSCOPE device to the US" said Fabien Rebeaud, PhD, Chief Scientific Officer of Abionic.

Understanding Sepsis

Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection. Infection leading to sepsis is mostly bacterial (95%), but can be fungal or viral as well.

Sepsis is a global health crisis, affecting 27 to 30 million people every year. 7 to 9 million of sepsis patients die – one death every 3 seconds. Depending on the country, mortality varies between 15% and more than 50%.

Mortality increases 8% every hour that treatment is delayed. If sepsis is diagnosed and treated in the first hour, the patient's chances of survival exceed 80%.

About Abionic

Founded in 2010, Abionic is a Swiss Medtech company that has developed a revolutionary nanofluidic technology, providing healthcare professionals with a fast, simple and universal diagnostic tool. Abionic's cutting-edge Nanotechnology enhances efficiency and versatility of standard ELISA tests to deliver optimal point of care (POC) treatment options with the potential to reduce the current biological techniques from macroscale to nanoscale in a multi-analyte environment.

Abionic's In Vitro Diagnostic (IVD) platform provides lab-quality results in 5 minutes from a single drop of blood at the POC enabling personalized diagnostics and the possibility of immediate treatment initiation. Other certified products already exist in allergy and iron deficiency today allowing for exploration of other targets for the IVD market of tomorrow.

For further information, visit https://www.abionic.com/.

About the technology underlying abioSCOPE®

The abioSCOPE® relies on Nanofluidics. Nanofluidics is the study of a liquid's behavior at the nanoscale. In such dimensions, it is possible to take advantage of the 'forced' biomolecular interactions happening in the nanospace in order to develop immunoassays able to detect minute concentrations of analyte in complex matrices such as blood. This allows for an immunoassay that quantifies pancreatic stone protein (PSP) from a drop of capillary whole blood in as little as 5 minutes. The specimen is mixed with a solution containing the fluorescently labelled detecting antibody. It then passes through a nanometric size channel in which anti-PSP antibodies are immobilized. These antibodies capture the PSP bound to the fluorescent detecting PSP antibodies. The abioSCOPE®, a tabletop size, easy-to-operate device, reads the fluorescence emission from the PSP sensor and converts the signal, employing advanced signal processing, into a concentration thanks to the assay's embedded, lot-specific calibration.

For further information, visit https://abionic.com/sites/default/files/pdf/scientific-paper.pdf

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