

Abionic: International Pivotal Study Successfully Demonstrates Diagnosis of Sepsis within 5 Minutes – 24 Hours Earlier Compared with Current Standard-of-Care

- A breakthrough on sepsis diagnosis on today's World Sepsis Day
- Every 3 seconds someone dies of sepsis globally. Sepsis is #1 killer at hospitals, it claims more lives than prostate cancer, breast cancer and AIDS combined.^{1,4,5} In the US there are more than 1.7 million sepsis cases every year, responsible for 270,000 deaths.²
- The World Health Organization (WHO) made sepsis a global health priority.⁴
- Mortality increases 8% every hour that the treatment is delayed. If diagnosed with Sepsis and treated in the first hour the patient has more than 80% survival rate.^{6,7}
- Abionic's 5-minute point-of-care sepsis test will help physicians to identify sepsis 24 hours earlier than today's standard of care. Early diagnosis of Sepsis is the difference between life and death.

Biopôle, Lausanne, Switzerland, 13th September 2019 – [Abionic SA](#), a developer of disruptive nanotechnology based rapid diagnostic solutions, announced today the successful completion of its multi-center observational study using Abionic's novel point-of-care Pancreatic Stone Protein (PSP) sepsis test on the abioSCOPE® platform. The results of the study show an anticipation of 24 hours for the diagnosis of sepsis compared to current standard of care.

Abionic is engaged in an ambitious clinical program demonstrating how the PSP test could lead to a better recognition and clinical management of sepsis.

The study was designed to establish performance characteristics of the PSP test in the early detection of sepsis. A total of 300 adult ICU patients at high risk of developing sepsis admitted to 14 ICU sites in the UK, France, Italy and Switzerland were enrolled. Bedside measurement of PSP on the abioSCOPE® clearly shows correlation with the onset of sepsis. During the study, the majority of patients who developed sepsis already showed high PSP concentration values 24 hours before the diagnosis with current methods. Time being critical with this condition, the outcome for patients could dramatically be improved with a gain of 24 hours.

The complete clinical data is currently in preparation for peer reviewed publication at the beginning of 2020.

“We are extremely proud to announce the successful completion of our pivotal sepsis trial and thank all the people who make this possible.” said Fabien Rebeaud, PhD, Chief Scientific Officer of Abionic. “Our study demonstrates that, from a drop of blood and in 5 minutes sepsis can be identified several dozen of hours upfront than today’s standard of care. This opens tremendous perspectives for the improvement of the diagnosis of sepsis and its timely, optimal clinical management, for the benefit of the patient.”

“I am deeply convinced of the potential of POCT with adequate sepsis marker that allows to speed up sepsis diagnosis. The PSP test on the abioSCOPE® platform is well positioned to achieve that ambitious but important goal,” Prof. Dr. Bruno François, Principal Investigator of the study from University Hospital Limoges, France, commented.

Dr. Giuseppe Nardi from Rimini Hospital, Italy, who also participated in the study, added: “The burden of sepsis is rising globally and claims up to 9 million lives every year – every 3 seconds a person dies from sepsis. Abionic’s early sepsis recognition test may tackle this issue and bring a valuable contribution to the improvement of sepsis management.”

Abionic is about to launch a multi-center clinical trial in the U.S to further establish the clinical value and fulfill FDA registration requirements. The first patient in is expected in October 2019.

The company’s vision is to have an abioSCOPE® in every single Intensive Care Unit (ICU) and Emergency Room (ER) to bring the right diagnosis immediately to patients.

Understanding Sepsis

Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection. Infection leading to sepsis can be bacterial, fungal, or viral, but usually 95% of cases are caused by bacteria.³

Sepsis is a global health crisis. It affects 27 to 30 million people every year, 7 to 9 million die – one death every 3 seconds. Depending on country, mortality varies between 15 and more than 50%. Many surviving patients suffer from the consequences of sepsis for the rest of their lives.^{4,5}

Mortality increases 8% every hour that treatment is delayed. If diagnosed with sepsis and treated in the first hour, the patient has more than 80% survival rate.^{6,7}

To improve sepsis management and reduce its burden, in 2017, the World Health Assembly and World Health Organization adopted a resolution that urged governments and healthcare workers to implement appropriate measures to address sepsis. The resolution determined that sepsis should be considered a medical emergency and that increasing the level of awareness of sepsis is essential.

About the PSP Sepsis Test on the abioSCOPE®

The pancreatic stone protein (PSP) sepsis test performed on Abionic's nanofluidic technology based point-of-care abioSCOPE® platform offers results in just 5 minutes with a drop of capillary blood for the earliest detection of sepsis, this enables physicians to make critical decision at the point of need. For further information, visit

<https://abionic.com/sites/default/files/pdf/scientific-paper.pdf>

About Abionic

Founded in 2010, Abionic is a Swiss Medtech company which has developed a revolutionary nanofluidic technology, providing healthcare professionals with a fast, simple and universal diagnostic tool –The abioSCOPE® is a portable device which is easy to use and enables HCP's to make medical decisions faster.

Abionic's In Vitro Diagnostic (IVD) platform provides lab-quality results in 5 minutes from a single drop of blood at the POC enabling precision diagnostics and the possibility of immediate treatment initiation.

Other certified products already exist in Sepsis, Allergy and Iron Deficiency today allowing for exploration of other infectious diseases.

Abionic already commercializes a test measuring the main respiratory allergens and total IgE in the US and Europe, and one used to detect iron deficiencies. Founded in 2010, Abionic developed its nanotechnology within the Swiss Federal Institute of Technology in Lausanne (EPFL). For further information, visit <https://www.abionic.com/>.

The World Sepsis Day

World Sepsis Day was initiated by the Global Sepsis Alliance (GSA) in 2012. The GSA is a non-profit charity organization with the mission to provide global leadership to reduce the worldwide burden of sepsis. World Sepsis Day is held on September 13th every year and is an opportunity for people worldwide to unite in the fight against sepsis. For further information, visit <https://www.worldsepsisday.org/>.

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