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First Patient Included in Multicenter Study to Evaluate SIRS-Lab's Diagnostic Test for Blood-Stream Infection



SIRS-Lab, a molecular diagnostics company based in Jena, Germany, announced the inclusion of the first patient in a 1000-patient clinical study evaluating their molecular pathogen test VYOO. The multicenter trial, performed in 11 key centers across Germany and initiated in February 2011, will deliver data about the utility of the PCR test compared to conventional methods to identify microbes in ICU patients with suspected sepsis.

Sepsis is one of the leading causes of death in hospitals. Every year, more than 60,000 patients die from sepsis in Germany alone. It occurs when microbes enter the bloodstream and trigger a severe inflammatory response by the patient's body. This is often life-threatening, and the search for the appropriate antibiotic or antifungal treatment can be a race against time. Traditional diagnostic methods can take several days to complete, and often miss the infection. With molecular diagnostics like the VYOO test, the microbe can be identified within hours, allowing rapid tailoring of the patient's therapy.

The biggest prospective trial of its kind to date in Germany will include more than 1000 patients in 11 centers. The study, led by the president of the German Sepsis Society Prof. Dr. Tobias Welte (Hannover), will deliver data about the sensitivity and specificity of VYOO compared with the current standard blood culture and the clinical diagnosis at the hospital. It will evaluate how VYOO supports the clinician's decision-making and delivers critical information to support early and targeted anti-infective therapy.

Barbara Staehelin, CEO of SIRS-Lab, said about the study: "In this study, Clinicians and Microbiologists in Germany's top centers combine efforts to improve critical care in sepsis. We are excited to now enter the clinical development stage with VYOO and are looking forward to see the test perform in a routine laboratory environment."

Results are expected in early 2012. Further information about SIRS-Lab and the study can be found on www.sirslab.com

About the study

Study title: An assessment of the potential clinical utility of a new multiplex-PCR assay (VYOO®) in the management of ICU patients with sepsis.

Principal investigator: Prof. Dr. Tobias Welte, Medizinische Hochschule Hannover, Germany

Study centers: 11 centers in Germany, mainly University Hospitals with Medical Microbiology laboratories

Expected patients to be included: app. 1000 with suspected sepsis

www.sirslab.com

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