Uniklinik RWTH Aachen is the first hospital to implement SphingoTec's innovative biomarkers in clinical routine with the aim of making intensive care diagnostics more precise

- *The biomarkers for the real-time assessment of kidney function (penKid®) and endothelial function (bio-ADM®) are pioneering new diagnostic pathways in critical care settings*
- *Following a positive initial clinical evaluation of penKid® and bio-ADM®, the University Hospital RWTH Aachen has transferred the innovative diagnostic tools into clinical routine*
- *The novel biomarkers enable a better diagnosis and monitoring of organ function*

Aachen, Germany and Hennigsdorf/Berlin, German, December 10, 2020 – The Uniklinik RWTH Aachen ("Uniklinik RWTH Aachen") has successfully translated the collaboration for research and biomarker validation with SphingoTec GmbH ("SphingoTec") into clinical routine. The routine measurements of the innovative biomarkers are providing organ-specific information for monitoring critical care conditions such as sepsis and acute kidney injury and support clinical decisions to improve patient outcomes.

Uniklinik RWTH Aachen is one of Germany's most modern hospitals due to the way it integrates diagnostics and therapy, research and teaching under the same roof. Following a patient-centric approach, Uniklinik RWTH Aachen has adopted innovative pathways in intensive medicine by introducing these new diagnostic tools for monitoring organ function of critically ill patients. The routine measurements of penKid® and bio-ADM® provide clinicians with more insights on the disease pathology and etiology of clinical symptoms and facilitate more efficient, timely, and adequate treatment.

Prof. Dr. Gernot Marx, the Director of the Clinic for Operative Intensive Care and Intermediate Care at Uniklinik RWTH Aachen explained: "Critically ill patients are highly dynamic with many complications interfering in the diagnostics process, thus a very challenging environment for introducing innovations. We have been looking for a long time for the right diagnostic tools to allow us a faster and better diagnosis, risk stratification, and monitoring of the disease progression so that we can provide the best available treatment immediately for acute cases. The first routine measurements do confirm the utility and value of these novel diagnostic biomarkers in clinical decision-making and ultimately in maximizing the patient's benefit. "

In intensive care units, 1 in 3 patients is developing acute kidney injury [1]. The existing diagnostic parameters for the determination of renal function or kidney damage, which are routinely used as standard procedure, have a considerable time delay or are influenced by inflammation or other diseases. These limitations are underlining the need for more precise tools to support clinical decisions. The biomarker penKid® offers real-time information about the kidney function with the first measurement and without being influenced by co-morbidities or the frequently occurring inflammation in critically ill patients [2,3,4]. Moreover, penKid® shows the best representation of the current kidney function, measured by the glomerular filtration rate (true GFR). [5]

World-wide, sepsis is accountable for 1 in 5 deaths [6]. Reduced organ perfusion in shock, which can be determined by existing laboratory values, is the culprit for the fatal course, but it can be induced by various factors. The loss of endothelial function is often a main cause for shock in sepsis, but it could not be detected by blood-based tests so far. The measurement of the bio-ADM® biomarker now allows for the first time the direct assessment of endothelial function in real time [7,8,9] independent of co-morbidities and inflammation, thus supporting precise and rapid treatment decisions.

Dr. Andreas Bergmann, founder and CEO of SphingoTec added: “We are excited that the initial clinical evaluation ended in a successful translation of the biomarkers into clinical routine. The comprehensive amount of routine data on our biomarkers collected by Prof. Gernot Marx and his team will allow us to deepen our knowledge of the biomarkers and to explore further application areas. Encouraged by this implementation of our novel diagnostic tools at the frontlines of medical care, we intend to offer them in a near future on a larger scale in other European countries.”

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Uniklinik RWTH Aachen

The Uniklinik RWTH Aachen is a supramaximal care provider that combines patient-oriented medicine and nursing, teaching and research at an international level. With 36 specialist clinics, 28 institutes and

five interdisciplinary units, the University Hospital covers the entire medical spectrum. Excellently qualified teams of doctors, nurses and scientists are competently committed to the health of the patients. The bundling of patient care, research and teaching in one central building offers the best conditions for intensive interdisciplinary exchange and close clinical and scientific networking. Around 8.000 employees provide patient-oriented medicine and care according to recognised quality standards. With 1.400 beds, the University Hospital treats around 50.000 inpatient and 200.000 outpatient cases per year.

About SphingoTec

SphingoTec GmbH ("SphingoTec"; Hennigsdorf near Berlin, Germany) develops and markets innovative in vitro diagnostic (IVD) tests for novel and proprietary biomarkers for the diagnosis, prediction and monitoring of acute medical conditions, such as sepsis, acute heart failure, circulatory shock, and acute kidney injury in order to support patient management and provide guidance for treatment strategies. SphingoTec's proprietary biomarker portfolio includes bioactive Adrenomedullin (bio-ADM®), a biomarker for real-time assessment of endothelial function in conditions like sepsis or congestive heart failure, Proenkephalin (penKid®), a biomarker for real-time assessment of kidney function, and Dipeptidyl Peptidase 3 (DPP3), a biomarker for cardiac depression. IVD tests for SphingoTec's proprietary biomarkers are made available as sphingotest® microtiter plate tests as well as point-of-care tests on the Nexus IB10 immunoassay platform by SphingoTec's subsidiary Nexus Dx Inc. (San Diego, CA, USA) alongside a broad menu of established and commonly used tests for acute and critical care.

About penKid®

sphingotest® penKid® measures Proenkephalin (penKid®), a stable fragment of the kidney stimulating hormone Enkephalin. penKid® has been demonstrated to be a real-time surrogate biomarker for glomerular filtration rate, the gold standard to assess renal function. Measuring penKid® blood concentrations allows for timely information on kidney function in critically ill patients. Early assessment of worsening and improving of renal function on intensive care units and in emergency departments allows adjustment of nephrotoxic drug administration and the initiation of kidney-protective strategies to prevent acute kidney injury and thereby improve outcomes. Learn more about penKid® at http://www.youtube.com/watch?v=6SYhs7it4R4

About bio-ADM®

sphingotest® bio-ADM® measures bioactive Adrenomedullin (bio-ADM®), a hormone maintaining endothelial function. The endothelium contributes to blood pressure and separates blood from the surrounding tissue. Elevated blood levels of bio-ADM® predict blood pressure break down and leaky vessels resulting in oedema. Imbalanced endothelial function is the major cause of shock ultimately resulting in organ dysfunction and death. Early identification of an imbalance in endothelial function allows guidance of vasopressor and diuretic therapy in critically ill patients to improve outcomes. Learn more about bio-ADM® at http://www.youtube.com/watch?v=52lrrRNb0k4

Press contact

Dr. Mathias Brandstädter
Leitung Unternehmenskommunikation
Uniklinik RWTH Aachen

Pauwelsstraße 30
52074 Aachen
Telefon: 0241 80-89893
mbrandstaedter@ukaachen.de
www.ukaachen.de

Ruxandra Lenz
Sr. Manager Marketing and Communications
SphingoTec GmbH
Neuendorfstr. 15 A
16761 Hennigsdorf
Tel. +49-3302-20565-0
press@sphingotec.de
www.sphingotec.com