

SphingoTec's kidney function biomarker penKid® accurately detects acute kidney injury in infants

- penKid® (Proenkephalin), a unique biomarker for the real-time assessment of kidney function
- Novel data now demonstrate that penKid® also accurately predicts acute kidney injury in infants and provides substantial additional value on top of the diagnostic standard of care

Hennigsdorf/Berlin, Germany, August 27, 2020 – Diagnostics company SphingoTec GmbH ("SphingoTec") announced today the publication of first data (1), proving that its real-time kidney function biomarker penKid® is a reliable biomarker for the diagnosis of acute kidney injury (AKI) in infants. With the incidence of pediatric AKI increasing globally, there is a high need for non-invasive, diagnostic solutions to improve the early diagnosis of AKI in children to prevent adverse events and improve recovery.

penKid® is an established biomarker for detecting AKI in adults. The current study shows that reference values for penKid® in children are much higher than in adults. However, when considering these higher reference values in critically ill children under one year of age, high or increasing penKid® concentrations accurately predict AKI and its severity.

Dr. Andreas Bergmann, CEO of SphingoTec, commented: "The data confirm, that penKid® predicts AKI also in challenging settings such as the pediatric critical care. In critically ill children, AKI has a high prelevance, is associated with poor outcomes and the possibilities for pharmacological intervention are limited. Therefore, the early detection of AKI is paramount in improving the prognosis for these children."

In children admitted to hospital, AKI is a common complication especially among those requiring intensive care, affecting up to 51% admitted to ICU (2). Pediatric AKI is often diagnosed too late for successful therapeutic interventions leading to adverse outcomes and chronic kidney impairment. The data from the recent study highlight that penKid® has the potential to address this diagnostic shortcoming. The study data add to the rapidly growing body of evidence in by now more than 30,000 adult patients, showing that penKid® is an early and accurate indicator for the worsening or improvement of kidney function. Importantly, penKid® is independent of inflammation and comorbidities and, as recently published, the most accurate surrogate marker for true glomerular filtration rate (true GFR) in patients with renal impairment (3) and hence ideally suited for the real-time assessment of kidney function and the early prediction of AKI.

References

(1) Hartman et al (2020), Proenkephalin as a New Biomarker for Pediatric Acute Kidney Injury - Reference Values and Performance in Children Under One Year of Age, Clin Chem Lab Med, doi: <u>10.1515/cclm-2020-0381</u>.



- (2) Sutherland et al (2015) AKI in Hospitalized Children: Comparing the pRIFLE, AKIN, and KDIGO Definitions, Clin J Am Soc Nephrol, doi: 10.2215/CJN.01900214.
- (3) Beunders, R. et al.(2020), Proenkephalin compared to conventional methods to assess kidney function in critically ill sepsis patients, Shock, doi:10.1097/SHK.0000000000001510

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 unique biomarker for real-time assessment of endothelial function in conditions like sepsis or congestive heart failure, Proenkephalin (penKid®), a unique biomarker for real-time assessment of kidney function, and Dipeptidyl Peptidase 3 (DPP3), a unique biomarker for cardiac depression. IVD tests for SphingoTec's proprietary biomarkers are made available as sphingotest® microtiterplate 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.

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